ROYAL COMMISSION ON MATTERS OF HEALTH AND SAFETY

ARISING FROM THE USE OF ASBESTOS IN ONTARIO

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THE FURTHER PROCEEDINGS IN THIS INQUIRY RESUMED PURSUANT TO ADJOURNMENT

APPEARANCES AS HERETOFORE NOTED

DR. DUPRE: Ladies and gentlemen, good morning.

Counsel, have you anything to raise before I greet the witness:

MR. LASKIN: I don't think so, Mr. Chairman.

DR. DUPRE: Do any other counsel have any matters to raise?

MR. LEDERER: Mr. Chairman, perhaps I might just introduce the gentleman sitting next to me. He is Mr. Mark Edwards from our offices.

I introduced Mr. Edwards to you because there may be occasions on which I cannot be with you when you are sitting, and on those days Mr. Edwards will be here in my place.

DR. DUPRE: Thank you, Mr. Lederer.

You are very welcome here, Mr. Edwards.

MR. LASKIN: I suppose there is one thing, Mr. Chairman. You know that the next time we sit will be a week tomorrow, when we will hear certain witnesses from Sweden, via Montreal. And just to tell the parties, it may be that we will depart from our usual format of having individual witnesses testify and we may have some type of panel discussion or testimony.

MR. LASKIN: (cont'd.) So just to tell the parties that may be coming.

DR. DUPRE: Thank you, counsel.

Well, it gives me great pleasure to greet Dr. Bailus Walker this morning. Dr. Walker is currently the director of the Michigan Department of Health. He has been the Director for Occupational Health Standards in the Occupational Safety and Health administration of the United States Department of Labour.

He has, in addition, served in at least two other American jurisdictions - New Jersey, District of Columbia.

He has also been a public servant in cities of Dayton and Cleveland, Ohio.

Altogether it is a privilege, on behalf of the Commission, to greet a most distinguished public servant. Dr. Bailus Walker, you are most welcome here indeed, sir.

Miss Kahn, may I ask you to swear in the witness.

DR. BAILUS WALKER, JR., SWORN

THE WITNESS: Mr. Chairman, members of the Commission. Let me first express my sincere thanks and appreciation for the opportunity to participate in these discussions dealing with occupational health standards and related matters.

I am aware that you have had very extensive discussions dealing with epidemiological aspects of occupational health. I know some of the very distinguished persons who have appeared before you, and I certainly will not want to repeat much of what they have said.

I would like to sketch in fairly broad strokes what I see as some of the issues involved in moving from epidemiological or animal data into the development of standards designed to protect workers...or at least to reduce the risk of workers exposed to various toxic substances.

THE WITNESS: (cont'd.) Now eliminating our exposure to toxic substances entirely can sometimes be accomplished by banning the use or the consumption of such material, but the alternative, and the usually-acceptable alternative to a ban, is a permissible or acceptable exposure level.

In fact, the primary thrust of the various legislative Acts was for the pertinent government agencies to determine the risk, and especially the health risk, posed by hazardous substances, and then to establish a safe exposure level below which health should be adequately protected.

When we get into carcinogens, that raises another issue which I would like to comment later on in the discussion this afternoon.

But the process by which these exposure limits are set and subsequently modified, this process is inherently difficult, it's slow, and contentious. There are generally conflicting forces of play with major economic interests, and professional reputations are also at stake in this process.

The available health-effects data are always inadequate and sometimes pathetically so. In terms of health data in support of regulations, the data from three types of research approaches are important.

First, the toxicological data from studies in animals, and now more and more, in vitro test systems; and secondly, clinical study data...that is, data derived from controlled experimental trials in human volunteers; and third, epidemiological data from studies in human populations.

Now, the three approaches are inter-related, and each plays an integral role in risk assessment and in determining safe levels of exposure, and they each bring their own special data to the process.

Animal data are critical, since they can provide

THE WITNESS: (cont'd.) data on high doses and test organs, for example, and they can also allow for the development of dose-response...a very, very important consideration in developing standards for the reduction of worker exposure to various toxic substances.

And yet, the problem of translating animal data to a human context is likely to remain with us, even when multiple-species information is available.

Clinical studies can be used to verify, under controlled conditions, estimated derived from field or population studies, and they can also be used to develop a dose-response series in some cases...and I underscore 'some cases'.

Epidemiological data can provide statistical association between agent and the health inpoint, be that inpoint carcinogenesis, teratogenesis, reproductive effects, etc.

However, such studies can be weakened by the problem of defining exposure. Now, most of the existing epidemiological studies on occupational exposure rely on retrospective methods, and we have had to use duration of employment as a measure of exposure, rather than some direct measure of exposure.

There is one notable exception I would like to point out to that, and that is two epidemiological studies on aresenic that were developed by...or conducted, I should say... by Peto and Enterline, and Lee and Fraumeni. Both of these studies provided evidence of a dose-response, a relationship for the carcinogenic effect of arsenic, and in fact these two studies met many of the requirements of an ideal epidemiological study and significant weight was placed on their findings by the Occupational Safety and Health Administration in developing a standard for occupational exposure to inorganic arsenic.

Perhaps one of the most vigorously-debated issues

THE WITNESS: (cont'd.) related to human studies is the comparative weight of positive animal studies over nonpositive human studies.

The Occupational Health and Safety Administration took the position in the cancer policy, which I'm sure we'll have more discussion about later on, we took the position that positive animal data should supercede human data.

Now, many of the observers hold the view that this position is scientifically unsound, but few of these observers make any distinction between the qualitative and the quantitative use, and interpretation, of negative or nonpositive studies.

I think in principle it is almost impossible to prove a negative with any study of a finite size. An epidemiological study, like any screening test, is an instrument of limited sensitivity. Thus, however well the study may be carried out, the most that one can conclude reliably is that it failed to show an effect within the limits of sensitivity imposed by the study design.

It is also important to emphasize that occupational epidemiology seldom provides results of a sufficient extent and accuracy to guarantee adequate negative evidence and to establish the usage of any substance is safe, in the face of experimental evidence to the contrary.

In other words, nonpositive epidemiological studies cannot, in principle, establish the safety of a substance that is under suspicion on other grounds. And thus in general, positive results obtained from one or more human epidemiological studies should be used to establish the qualitative inference of carcinogenic hazards in human populations.

On the other hand, a positive animal data should supercede nonpositive human data in qualitative identification of a hazard.

THE WITNESS: (cont'd.) Now, rarely will nonpositive epidemiological results provide evidence to offset scientifically-evaluated positive results of carcinogenicity observed either from other animal studies or from experimental studies in test animals.

Now, using these research tools that I have briefly described, to identify the hazards, I think one of the next things that we must do is to estimate the risk. The assessment of cancer risk, for example, in the work environment involves at least two phases - one, the identification of a risk and the estimation of the risk in terms of dose-response for a particular chemical, and two, the evaluation of what degree of risk, for example, the level of exposure, should be accepted.

As you well know, there are many scientific, philosophical and political problems included in the hazardous undertaking of the cancer risk assessment.

This issue took on added significance in the United States when the Supreme Court, in July of 1980, held that OSHA exceeded its standard-setting authority because it had not shown that lowering the benzene standards from ten parts per million to one part per million was reasonably necessary to provide safe and healthful employment.

The Chief Justice, joined by two associate justices, concluded that the burden was on the regulatory agency to show that on the basis of substantial evidence that it is at least more likely than not that long-term exposure to ten parts per million of benzene presents a significant risk of material impairment.

The court said by empowering the United States Secretary of Labour to promulgate standards that are reasonably necessary or appropriate to provide for a safe and healthful workplace, the Occupational Health and Safety Act of the United States implied that before promulgation of any standard that we,

THE WITNESS: (cont'd.) the regulatory agency, must make a finding that the workplace in question is not safe.

But safe, said the court, and I underscore this, is not equivalent to risk-free, and therefore the court concluded that before we can promulgate any permanent standard we had to make a threshold finding that the place of employment is unsafe in the sense that significant risks are present and that these risks could be eliminated by a change in practice through the regulatory process or some other means.

Now, the court made it clear that the regulatory agency should decide what is a significant risk and that the criteria for the judgement of that risk does not have to be based on scientific certainty.

The court indicated that the regulatory agencies could rely on scientifically reputable opinion and conservative assumption, and need not await evidence of actual human disease.

It is important to point out here that what the court did not know was that during the period of the development of the benzene standards that workers of a large U.S. chemical company exposed to less than ten parts per million had been found by the company's own scientists to have significant increase in chromosome damage. This information was withheld by the company until after the Occupational Safety and Health Administration had published the filed benzene standard and it was too late to include the information in the administrative record for the court review.

So given that critical evidence was withheld from the agency, it is difficult to blame the agency for not doing a better job of quantifying the risk under ten parts per million of benzene.

I think the benzene example shows the conflicting and often political role that industry plays in occupational health

THE WITNESS: (cont'd.) regulations. Some segments of the industry have failed to gather, or have withheld or distorted or manipulated, evidence which would have strengthened the case for lower occupational exposure levels to hazardous substances, and yet when the standard was finalized the industry used in its suit to block its implementation argument that there is inadequate evidence of significant risk.

Now, one might argue that an acceptable risk is a frequency of events not exceeding the probability of death by a natural disease or due to great age. This definition does not, however, recognize the fact that the probability of death by natural disease is not geographically or otherwise uniform in human populations. Nor does this definition recognize the time of occurrence of the disease. It cannot be the same thing to die of an infectious disease at thirty years of age as it is to die of the same disease at ninety years of age...not to the individual, his or her relatives or to society.

Furthermore, and perhaps even more important, the definition does not recognize the fact that some diseases such as cancer may be increasing in incidence with time. And this means that background levels will be different after ten years than it is today. Is this in itself acceptable?

Now, our attitude to a risk varies with the type of risk. A voluntary risk might be more easily acceptable than an involuntary one, especially if the benefit to the person at risk is great. A risk posed by nature might be accepted in a different way than a manmade risk. A very small risk, and risk at distance and in time and space, are difficult to rationally perceive and experience. I think one's personal experience of an injury and the suffering that follows may have a great effect on one's willingness to reduce that particular risk.

I think it should also be remembered that

THE WITNESS: (cont'd.) occupational risks such as cancer risks are often imposed on workers who are not informed or maybe misinformed about the risks, and who have no other choice than to work in that particular job.

In the work environment, risk and benefit do not necessarily involve the same individual. One individual may be exposed to the risk factor, while perhaps not getting much benefit out of the work, and while another person not exposed to the risk factor at all receives the main part of the benefit.

So the regulatory authority is then the last corner of the risk triangle.

Now a fundamental question that often surrounds the standard-setting process is how much health protection should we provide for workers.

For example, in establishing the standard for worker exposure to coke oven emission, we in the United States were dealing with a known cancer risk to workers. That was clearly acknowledged by the steel industry itself.

The regulatory agencies set a standard which represented the extent of the industry's ability to reduce worker exposure to coke oven emissions through the rehabilitation of existing equipment - which was coke oven batteries - and through the proper design and construction and the operation of future coke oven batteries.

The steel industry representatives agreed that coke oven emissions caused cancer. They also agreed that industry could afford the cost of compliance. But the industry concluded that the standard and the protection it provided was not worth the cost of compliance.

It was not a question of how much industry could afford. It was a fundamental question of how much protection should workers have.

THE WITNESS: (cont'd.) Now, in this connection, Lester Lave (phonetic), who is a long-time student of regulatory issues and currently Senior Fellow at the Brooken's Institute in Washington, has identified six frameworks for making regulatory decisions: no risk, technology-based standards, risk risk, risk benefit, cost effectiveness, regulatory budget and benefit cost.

He applied some of these or several of these to the coke oven emission standard that was published in 1975. The no-risk framework would call for a closing of coke ovens unless emissions could be reduced to zero.

The technology-based decision framework would call for the best available control technology, and while there is some dispute about the availability of technology that will meet the standard, a case can be made or could be made that even better control technology is currently available.

Now the risk-risk framework, in that the beneficial health effects are considered along with the adverse health effects. In the case of the coke oven standards, the risk risk is not applicable here since there is no opposing risk to workers which might offset that from coke oven emissions.

A risk-benefit analysis helps a little, as the tradeoff between the price of steel and the risk to coke ovens is somewhat complicated. A conventional approach is to examine the risk of these workers, meaning coke oven workers, in relation to the risk of other workers.

Benefit-cost analysis was used implicitly in setting the standards. There was considerable dispute about the cost of meeting the standard, and there was some dispute about the number of lung cancer deaths that could have been prevented.

Now, each health standard is fundamentally an attempt to maximize the overall societal benefits and to minimize the overall societal cost associated with the use of toxic substances

THE WITNESS: (cont'd.) The methodology to achieve this result cannot always be expressed in a rigid formula within which we can place precise numbers and get a definite answer or have a definite answer emerge.

Rather, the methodology for maximizing societal benefits and minimizing societal costs depends largely on legislative and agency judgement on policy and value decisions that are embodied in the statute, and upon the implications of alternative courses of action.

The broad central questions to be grappled with are one: whether the current worker exposure to a substance merits a standard to reduce exposure, and two: if so, how stringent should the terms of the standard of the regulatory action be.

The delicate balance of societal benefits and costs comes into play first in deciding what kind and how much evidence will be required to answer "yes", in quotes, to the first question.

And second, in deciding where on the continuum between no regulation and an outright ban to establish the terms of a standard regulatory action.

Now, for a number of reasons cost and benefit are presented in different terms, and unfortunately, few regulatory agencies can balance the relative worth of two hundred and fifty million dollars in the cost of compliance, for example, versus two hundred and fifty lives that would be saved if a standard or other regulatory strategy is complied with, even if the data are adequate to predict with certainty the reduction of health risks that would result.

Another difficulty is that almost the sole source of information on the cost of compliance is in the hands of those to be regulated by the standard. The cost of compliance is an important consideration...I do not intend to convey here that it is not...and it bears on two aspects of standard setting.

THE WITNESS: (cont'd.) First is the question of feasibility. That is, what can reasonably be achieved by the industry.

This assessment obviously requires cost data, it requires an understanding of the nature of the industry, its composition, the technology available today, the degree of worker exposure, and the extent to which this exposure should be reduced. These, as you have probably concluded, are complex issues.

The second element is one of time. Often the cost of compliance can be extended over a long period through the development of an orderly time-phasing process, whereby over time industry will change production equipment and facilities and these changes will ultimately result in a reduction in worker exposure to hazardous material.

Although the cost of compliance is an important consideration, the United States Supreme Court held in the American Textile Manufacturers Institute versus the Secretary of Labour... this is better known as the cotton dust case and I think some of you are familiar with it...that cost-benefit analysis by the regulatory agency is not required in promulgating an occupational health standard because feasibility analysis is required.

The plain meaning of the word feasibility, the court said, is 'capable of being done'.

In effect, the United States Congress itself, in writing the Occupational Health and Safety Act, defined the basic relationship between cost and benefit by placing the benefit of the workers' health above all other considerations, save those attained...save those making attainment of this benefit unachievable.

Any standard based on balancing costs and benefits that strikes a different balance, the court said, than that struck by the Congress would be inconsistent with the command of the

THE WITNESS: (cont'd.) Occupational Health and Safety Act.

So the Act specifically states that:

"The regulatory agency shall issue the standard that most adequately assures that no employee will suffer material impairment of health, limited only by the extent to which this is capable of being done".

In my view, Congress, in writing the Occupational Safety and Health Act, was concerned that that piece of legislation might be thought to require achievement of absolute safety, an impossible standard, and therefore insisted that the health and safety goals be capable of economic as well as technologic accomplishment.

I think the legislative history demonstrates conclusively that Congress was fully aware that the Act would impose real and substantial cost of compliance on industry, and believed that such costs were a part of the cost of doing business.

In much of the political and economic discussion of occupational health and safety standards, the fact that prevention of occupational diseases and disabilities is a part of the cost of doing business, this element is often overlooked in much of the discussion about standards.

There is no argument with the fact that compliance should be the foundation of regulations in the health field, and not only the occupational health field, but in other areas of the health arenas.

But I should suggest to you that the good science is by no means an adequate or a sufficient basis for many of the decisions which must be made in the promulgation and in the implementation of health standards.

For example, once we have identified the hazard and

THE WITNESS: (cont'd.) estimated the risk, we must then determine whether or not it is socially acceptable, and if so, at what level. But in considering this, we are no longer in the realm of the scientists. This is a policy decision that is often made through our political process.

I think it should be emphasized, finally, that in the final analysis the most difficult questions that policy makers must decide in setting health standards are not the scientific questions. The science may be murky, but the decisions on the basis of this science are much more easily arrived at than the political and the economic policy decisions.

Thank you very much.

MR. LASKIN: Thank you very much, Dr. Walker.

I suppose we should discuss what our agenda is, Mr. Chairman, in terms of how we proceed. Certainly one alternative would be to break now for a short period of time, bearing in mind that Dr. Walker has been flying since very early this morning, and perhaps resume at, say, one-thirty or thereabouts, and carry on for the balance of the afternoon.

DR. DUPRE: I think the principal interests of this Commission lie in the humane treatment of Dr. Walker.

MR. LASKIN: I agree.

DR. DUPRE: Does that strike you as reasonably humane, Dr. Walker?

THE WITNESS: Yes, it's fine with me. I am at your disposal.

DR. DUPRE: Thank you indeed, sir. We shall break, then, until one-thirty.

MR. LASKIN: One-thirty.

Thanks, Dr. Walker.

THE INQUIRY RECESSED

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THE INQUIRY RESUMED

MR. LASKIN: Sorry for being late, Mr. Chairman.

EXAMINATION-IN-CHIEF BY MR. LASKIN

Q. Dr. Walker, can we, as a prelude to discussing the cancer policy and some specific issues under it, can we step back into the precancer-policy timeframe for OSHA and could you just sketch in for us what OSHA's initial approach was to identifying occupational hazards, and regulating them, and, I suppose, ultimately linking the problems that you had in the beginning to the evolution and rationale for the cancer policy?

A. Yes.

There are several forces behind the development of the cancer policy. OSHA was in the standard-setting process since the early part of 1970, and several things became clear in that process. One was that it was a slow and contentious process. Two, that the record on which the agency wanted to develop standards was usually voluminous, and yet many of the key questions that the agency wanted answered were not answered in the proceedings.

In ten years of existence I think the agency had promulgated twelve, thirteen, fourteen standards, and on analyzing the problem the agency discovered that it was litigating and debating over and over again the same kinds of issues.

For example, whether or not animal data, animal research data, could be applied or translated to man in the standard-development process. Each time the agency attempted to promulgate a standard, and asked for public comment and held public hearings, that issue had to be reargued again and again and again, which slowed down the process.

Another issue that had to be debated again and again and again was whether or not there was a threshold...is there a level below which a cancer-causing agent would not cause cancer.

A. (cont'd.) That issue was debated again and again.

Several of these kinds of issues led the agency to conclude that if we are to make any progress at all in promulgating and implementing standards to protect the workers, it is necessary to try to put some of these issues to rest. And it was that factor, among several others, that led the agency to the development of a cancer policy where this issue would be put to rest.

The other issue that often came up was the quality of data, and I refer to my earlier comment- the whole question of epidemiological data, positive and nonpositive epidemiological data.

What were the meaning of those data? What is considered an acceptable epidemiological study?

Many people would come in and present their epidemiological investigations, the record would be full of studies, and yet when one analyzed those studies and tested them against certain very specific criteria, we would find, for example, that the observation period for the epidemiological study was not long enough. When you are dealing with a cancer-causing agent we are talking about latency periods up to twenty to thirty years, and some of the epidemiological studies would come in with a five, ten year observation.

Population size was another factor. Some of the epidemiological studies that were introduced into public record did not contain an adequate sample of the population to be studied, and so as a result of all of these issues, the agency promulgated, proposed, this cancer policy, which was debated extensively in Washington and around the country, and it is one of the few documents where you really have a comprehensive review of a large percentage of the issues involved in the

A. (cont'd.) classification, the identification and the regulation of carcinogens.

So it was those issues that led the agency to develop the cancer policy.

Q. Just to come back briefly with something you said before, were there some issues that the agency felt were not being dealt with in specific rule-making proceedings before the cancer policy, that it felt should have been dealt with? Or was it simply that issues were getting dealt with again and again?

A. Issues were...we were spending a lot of time rearguing the same issues. Time and time again the issue of translating animal data to humans, or applying animal data to humans, had to be discussed, and that was slowing down the standard-setting process.

I think that, along with several other issues that I have pointed out, the agency felt it needed to have addressed and this document, the cancer policy, attempts to do that.

Q. I take it the cancer policy itself was subjected to the same rule-making procedures and opportunities for parties to intervene and so on, as they would in respect of any specific rule promulgated for a specific company?

A. Yes. The agency proposed and then put out for public review...there were very extensive public hearings on the cancer policy...and practically every expert in the quote, unquote, "Who's Who" of carcinogenesis participated in those discussions.

The hearing record was roughly two hundred and fifty thousand pages, which had to be analyzed and ultimately translated into this document. So it did go through the regulative process of proposal, public participation, cross-examination of the witnesses - the same kind of analysis and review that the standard would go through.

Q. And what role, if any, did NIOSH play in that process?

A. NIOSH participated in presenting and analyzing some of the critical issues. For example, the dose-response problem as related to epidemiological studies. They were able to draw on their research experience and make a valuable contribution to the public record.

They had had, for example, experience in conducting hazards analyses in various industries. They were able to bring that kind of information into the hearings.

They also participated in coming up with criteria for a good, positive epidemiological study...epidemiological study design.

So they were very active in this whole process. Not only were they active in the development of test policies, but when we got into the review and...the development and the review...of the candidates' list, NIOSH was a part of that review team.

In the cancer policy there is a requirement for the Secretary of Labour to convene a scientific review panel to resolve issues related to the prosecution and the identification of cancer-causing substances.

NIOSH is a member of that review body. The National Cancer Institute and the National Institute of Environmental Health Sciences, they are the three advisors to the Secretary of Labour on the identification, classification of cancer-causing substances. So they have a very active role.

Q. Could you just sketch for us very briefly the main elements of the cancer policy as originally promulgated?

A. Yes. First there was the classification of potential cancer-causing agents. We had originally proposed four classifications. The first...in classification number one would be those substances where there was a substantial amount of evidence, and while I dislike the term 'confirm', I want to use it here... confirmed evidence of carcinogenesis.

A. (cont'd.) In category two, the evidence is not quite as strong as it was in category one. And then we had proposed a category three, which was even weaker than...the evidence was even weaker than it was in category two.

Then category four, we had proposed that all the substances that were not used, manufactured or processed in the United States...they were being used, processed in foreign countries... we felt that we should address those.

But when we published the proposal, these four were included, on public hearing the overwhelming evidence suggested that we ought to limit our concerns to two - confirmed or suspected - and that a lot of our efforts should therefore be spent into moving the substances in category two into category one, or we delete them from the list.

So the classification of carcinogens was a key part of that. The other element...and let me back up, I should have said the identification...what kind of evidence is acceptable in the identification of a cancer-causing substance.

Much debate...a very extensive amount of information in the record...on animal data versus human data. A very extensive amount of information on the record on nonpositive human data versus positive animal data...a lot of debate about that. Industry came in with a lot of information, the academic community...all were concerned about this basic issue.

So the policy centrally sets out what information the agency would accept in identifying a cancer-causing agent as a category one or a category two carcinogen.

The other element of the policy, identification and classification...the other element of the policy that caused a lot of concern is the issue of a freeze in science. There was some feeling that promulgating this policy in 1980 would freeze

A. (cont'd.) science at 1980, and that if there were developments in 1985 or 1986 that would somehow negate what is here or change the scientific information that was here, that there would be no way to do it.

So there is now in this policy three ways in which that policy can be changed to reflect current scientific thinking. One of the ways that it can be done is that any member of the public, or any group, can petition the Secretary of Labour to have that policy reviewed. If a scientist in an academic institution has new information, he can petition the Secretary of Labour to consider that information and determine whether or not that cancer policy ought to be changed in light of that new information.

Q. Is that a matter within the discretion of the Secretary of Labour...?

A. That's a matter within the discretion of the Secretary of Labour.

Another avenue for change in that policy and keeping it up to date with current scientific thinking is that every three years...at least every three years...the Secretary of Labour shall ask the director of the National Cancer Institute, the director of the National Institute of Occupational Health and the director of the National Institute of Environmental Health Sciences to meet and review that policy and determine whether or not it is current with scientific thinking.

Finally, another avenue for change in this, is that the Secretary may on his own motion, without petition, without comments and recommendations from the scientific review board, direct that that policy be reviewed and amended or changed so that it is consistent with current scientific thinking.

Those were the major elements of the policy.

Q. And to step back, on the crucial issues that have been debated prior to that - for example, take your first

Q. (cont'd.) issue, human versus animal evidence - do I take it that OSHA came down on the side of treating human data and animal evidence equally?

A. No. We came down on the side of animal evidence. Our view has been that there are very few good epidemiological studies. One of the problems that we obviously have in epidemiological studies is dose.

While we may know a worker is exposed, what is the dose to which that worker has been exposed? Most of the studies that have been done are retrospective studies, and it becomes very difficult to try to reconstruct - even on the basis of employment data, duration of employment, it becomes very difficult to try to reconstruct dose data.

Now, we did recognize that human data would allow us to make some qualitative inferences, but would not help us very much in trying to make quantitative inferences.

Another more important point, I think, a realistic point...

Q. I'm sorry. Can I just stop you on that, because that's a concept that we certainly did not hear anything about last summer when we heard a lot of epidemiological evidence, and I think it's fair to say what we heard was it's true that the data wasn't very precise and wasn't very good, but one estimate or guesstimate one could make would be to extrapolate along a linear dose-response curve from an epidemiological study.

The one thing we didn't hear was that you could use animal evidence in any quantitative sense to make any dose-response extrapolation to the human situation, and indeed, I think the evidence we heard was that animal evidence might be helpful in a qualitative sense, but no further.

If I understand a little of what you are saying, you seem to be suggesting precisely the opposite.

A. Yes. That in animal data in controlled experiments we know the dose. We can measure the dose, we can know exactly what those animals are exposed to.

In humans it's very, very difficult in work settings to measure that dose. Plus the fact that we have, more often than not, humans who are exposed to multiple doses of different kinds of substances.

The...obviously one of the problems we have in animal data is that we...you might have seen this before...is that animal data, we usually give very high doses. The problem that we have is, and where a lot of disagreement comes in, is what happens to this dose-response curve down at this level.

There is overwhelming evidence that this is linear. There has been some suggestions that this takes the form of the hockey stick at this lower level, but the majority of the scientists say that this is linear. And therefore, there is...we have not been able to identify a threshold and we must then assume that any amount, any amount, of a cancer-causing agent can cause cancer, and that is why the agency in its policy said that we must regulate cancer-causing agents to the lowest feasible level, lowest feasible economically, lowest feasible technologically.

Q. What does the agency say on this issue of animal versus human evidence on the problem of extrapolating from animals to humans, to put it in its simplest terms? Quantitatively?

A. Yes. We said that it can be done, but you've got to recognize that there are some differences in human populations and animal populations and that has to be taken into consideration in the extrapolative process.

But if we are going to do risk assessment as mandated by the Supreme Court in the benzene decision, this is

A. (cont'd.) the kind of data that we are going to have - animal data. The fact of the matter is that most of the cancer-causing agents that have been found to cause cancer in humans have also been found to cause cancer in animals.

So a lot of weight in the cancer policy is put on animal data. We would also consider the fact that at some point we may not have, if our Occupational Health and Safety programs are effective, we may not have human data and we will be dealing with, by and large, animal data. And if we divided the scientists up, a good eighty-nine point nine percent of the scientists would come down on the side of animal data.

Q. To take a specific example which concerns this Commission really is, can you help me and tell me what OSHA's approach might be on asbestos, on whether one should, from a regulatory point of view, differentiate between the different types of asbestos fiber?

There is at least some human epidemiological evidence which would suggest, for example, that crocidolite may be more hazardous than chrysotile. The animal evidence seems not to differentiate. They seem to be equally hazardous.

How would the agency, and how would the cancer policy, grapple with that kind of issue?

A. We would not attempt to distinguish between fiber types. We would regulate all fiber types. Again, I go back...

Q. Equally?

A. Equally. I would again go back to what the animal data shows. You suggested, and I think...I believe Leman testified here...supports this view.

DR. DUPRE: Dr. Walker, coming back to that general proposition of extrapolating from animal data, I noticed in your Journal of Environment Health paper, January/February 1982,

DR. DUPRE: (cont'd.) a quite recent paper, that your statement that for these extrapolations, mainly the extrapolations from the high doses to which animals are exposed, to extrapolate down to the low doses...

MR. LASKIN: Tab eleven.

DR. DUPRE: ...to which humans are exposed, I notice the statement that for these extrapolations there are a variety of mathematical models.

I was wondering if you could comment at all on the utility of these mathematical models from a regulatory standpoint?

THE WITNESS: Yeah. It would be my view that in some situations either one of the models, mathematical models... and I don't want to go into the details of the models...but either one of those models would be applicable...as long as we recognize that they are our best estimate.

I think that's the point that has to be made clear in the standard-setting process, that we arrive at one part per million benzene, we are not suggesting here that one part per million is an absolute guarantee against asbestos-related disease. Nor are we saying that if you are exposed to two parts per million you will get asbestos...you will develop asbestos-related disease.

These are by and large general guidelines, and are not absolute guides. I think too often we try to give the impression...at least some try to convey the impression...that these are absolute values. They are based on scientific interpretation by scientists in the field. In many cases the data from which these numbers were developed are not absolute.

So I would say that in using the models one must recognize the limitation of those models, and recognize also that there is a degree of uncertainty in this whole process.

In fact, this is one of the reasons why the agency

A. (cont'd.) resisted so long doing risk assessment, because we recognized that there are a number of uncertainties in doing risk assessment, and if we guessed wrong we may not know it for twenty, thirty years from now - based on the latency period of chronic occupationally-related diseases - and so we tried to steer clear from that.

We also tried to steer clear from cost-benefit, because we did not necessarily want to try to put a value on human life.

DR. DUPRE: Dr. Mustard.

DR. MUSTARD: Could I ask you about what you mean by models? I would presume that from your animal experiments you have data which would say five or six groups of animals are given different doses of exposure and show certain incidents of cancer, and you can therefore plot dose against response.

THE WITNESS: Yes.

DR. MUSTARD: It just seemed to me that has to be the basis of all your models - you have to put that in. Is that correct?

THE WITNESS: Yes.

DR. MUSTARD: Then you would then make an assumption, you would make an assumption that there is no threshold and extrapolate a line from those data points back to your origin.

Would that be model one - a no-threshold approach?

THE WITNESS: Yes.

DR. MUSTARD: Now, would you, in this, give consideration, however, that data could be expressed in another way, that it could be an exponential function, for example, that the response increases logarithmically against the dose. Is that what you mean by...would that be an alternative model?

THE WITNESS: Yes. That's a model. That's an

THE WITNESS: (cont'd.) approach.

The first question that you are trying to answer here...

DR. MUSTARD: No, but what I'm trying to get at is, you are really saying, you are using the term models, as different ways of assessing the relationship between dose and response, is that correct?

THE WITNESS: Yes. Different mathematical models, and you are trying to answer the question - if animals are exposed at this level what is the likelihood, or what is the probability, that we will get X number of cancers from some substance, and in this range where humans are normally exposed... very few humans are exposed at these high doses...is where the experimental animals are exposed - we are trying to answer the question, based on this, what is the likelihood, or how many cancers would we expect, what are the probabilities of the development of X number of cancers in this range where humans are exposed?

That's the question that these models are trying to answer, and you can plug in these numbers into these models... there are all kinds of complex computer models...you can plug that in and get some numbers, and based on the animal data, based on what we know about lifetime exposure, etc., etc., we would expect X number of cancers per year on exposure to these substances.

DR. MUSTARD: And your models all assume that there is no threshold?

THE WITNESS: There are some that assume that there may be thresholds.

DR. MUSTARD: Which do you use when you are doing the extrapolation from animal data?

THE WITNESS: We usually use the no-threshold model.

DR. MUSTARD: And the linear relationship?

THE WITNESS: And the linear relationship.

DR. DUPRE: Dr. Uffen?

DR. UFFEN: Could I go back to one thing about the animals? My recollection, if it's right, on animal data is that one of the problems is that the latency period for asbestos illness is longer than the normal lifetime of the animal you use to test. How do we...have you any advice on how to cope with that?

THE WITNESS: One has to, again, make some extrapolations...looking at the animal lifespan versus human lifespan and make some extrapolations.

That is probably one of the most contentious issues - making that leap from animal data to human data, considering lifespan and several other biological factors.

DR. UFFEN: Have I got it right? If you use rats or guinea pigs that normally only live about four or five years, well, if they all die you mustn't attribute it invariably to that without taking account...

THE WITNESS: But you can...and without getting too detailed scientifically...but you can make some extrapolations between those two, recognizing, of course, that the high dose here and the short lifespan are factors that must be taken into consideration.

I think when one sees a good animal study, a well-designed animal study, and the results say that this substance causes cancer, the logical question is, well, it has not been caused in humans.

My response would be, not yet.

DR. UFFEN: Could we use animal experiments then to study the problem that has been in front of us - the short, but intense, exposure of a human worker?

THE WITNESS: Yes.

DR. UFFEN: You think you could?

THE WITNESS: You can.

DR. UFFEN: Could you elaborate? How long did it take for the cancer to develop in an animal - say a guinea pig? Is it the same latency period as for humans?

THE WITNESS: You may get some development in eighteen months to a two-year period.

DR. UFFEN: In other words, you don't have to wait until it dies?

THE WITNESS: You don't have to, no. No, you can sacrifice the animal before its death and get evidence of carcinogenesis.

DR. MUSTARD: Just to sort of comment on the question...latency in humans does not necessarily relate to latency in animals. In other words, the latency period to produce carcinogenesis in an animal, say for asbestos, is not the same as the latency period for man. I presume...

THE WITNESS: No. Not a year-to-year direct relationship.

DR. MUSTARD: Well, aging is one of the factors in terms of susceptibility, and a rat ages fairly quickly compared to you and I and therefore he moves into that period of susceptibility fairly quickly, and I would presume you would take that into account in doing your analysis, is that correct?

THE WITNESS: Yes, you would.

MR. LASKIN: Q. So I take it, then, that in terms of OSHA's approach to risk-risk assessment that quantitatively the only evidence that you are using is animal evidence, animal experiments, and human epidemiological studies are used for qualitative purposes, to identify a possible carcinogen? Is that putting it fairly, or have I put it too strongly?

THE WITNESS: A. No, too strongly. It's not the only evidence we use.

In doing our risk assessment for arsenic, we happened to have - one of the few times the record was clear, the public record was clear on dose-response - we happened to have in the two studies of Peto and Enterline, and Lee and Fraumeni, we happened to have data that would allow us to calculate, to develop a dose-response curve.

It was there that we were able to use both human...I mean human data, because there has been no evidence of arsenic producing cancer in rats.

So we had animal...I mean human data that we used.

Q. Let's bring it down to asbestos, and help me if you can. I guess number one, has the administration done a risk assessment on asbestos, and number two, even if it hasn't, are you aware of any epidemiological studies in the asbestos field that might qualify for risk assessment in the same way that Peto and Enterline and arsenic....

A. I think Selikoff's group has done some work in this area, and there may be some British studies. I can't recall specifically, but there may be some British studies in this area.

Q. Do you know whether the agency has done a risk assessment in respect of asbestos, using animal data?

A. The agency has done, yes. In fact, shortly after the benzene decision was handed down by the Supreme Court, the agency did a risk assessment on asbestos.

Q. Has that been made public, do you know?

A. No, I don't think it has been.

Q. That was after your...

A. It was done while...yeah, it was done while I was there, because I wanted to see how a risk assessment would

A. (cont'd.) look, and in terms of the court's decision on benzene, so we did a risk assessment.

Q. I suppose...do you know whether...I mean, is it available? For example, would it be available to this Commission?

A. I think it would be. Let me say I think it should be. It should be.

Q. It is still, I take it, lodged within the internal administration of the agency?

A. Yes.

DR. MUSTARD: I have a question. Don't you have a freedom-of-information-or-something clause that it would have to be made available if somebody in your country asked for it?

THE WITNESS: Sure.

DR. UFFEN: Could I ask one that is related to the risk assessment? In one of your articles that dealt with this, tab eleven, the object of the estimation of risk is, "The evaluation of what degree of risk should be accepted."

All these estimates involve inter-related considerations of statistics, current public policy and, most tellingly, nonquantifiable penalties as to pain and grief, bereavement, which after all are among the major reasons we try to eliminate cancer.

Now, this is a very, very difficult area, but have people tried to include in risk assessment such things as pain, grief and bereavement? Is that just an observation you made?

THE WITNESS: That's really just an observation. What we do, though, is in getting this number up here from risk assessment, that X number of cancers per year are likely to occur at this level of exposure, once we get that number one has to ask is that acceptable.

THE WITNESS: (cont'd.) It is then that you take into consideration what does it cost to reduce this number from X to X over two, and consider in that cost equation, is this whole issue of pain and suffering, the loss of that family member, etc., all those are taken into consideration.

In helping society...maybe not the scientist...but in helping society, make the determination, make the decision as to whether or not it wishes to spend one more million or billions of dollars to reduce this X by X over two.

So it's a kind of nonquantifiable element that comes into play in making a society judgement on whether or not we want to tolerate X number of cancers per year.

MR. LASKIN: Q. Does the agency take it that one of the Supreme Court's decisions in benzene was that a risk assessment must be done in every case, or only in those cases where there is enough reliable data to do one?

In other words, can the agency nonetheless come to a decision and promulgate a standard on a specific substance it thinks is carcinogenic, without doing a risk assessment, in the wake of the benzene case?

THE WITNESS: A. In our interpretation of that decision, yes. Because there is an interesting footnote in that decision which says that doing, conducting a risk assessment should not put the agency in a mathematical strait jacket. That's a well-underlined and well-used footnote.

The court said it was not looking for mathematical certainties, that the agency could use some assumptions, some very sound assumption now, obviously, but it was not looking for mathematical certainty.

So I think we interpreted that as meaning yes, we can, without a hard and fast risk assessment.

DR. MUSTARD: Can I pick that up? As I understand

DR. MUSTARD: (cont'd.) your vinyl chloride regulation, it is not based on a real risk assessment of humans because the epidemiological data doesn't exist. It's based on the fact that it's a carcinogen and your control level of one part per million, which I believe it is, was based on the technically-achievable level, the lowest technically-achievable level. Is that correct?

THE WITNESS: Lowest achievable level. Yes, that's correct.

DR. MUSTARD: And that is not a risk assessment?

THE WITNESS: No.

DR. MUSTARD: That was before the benzene decision, however?

THE WITNESS: That's right.

DR. MUSTARD: If that was taken to the U.S. Supreme Court, do you think it would be thrown out because it doesn't have a risk assessment?

THE WITNESS: After the benzene decision, it probably would be. It probably would be.

MR. LASKIN: Q. As I understand, what the court essentially said in benzene...and correct me if I'm wrong...was that the Secretary of Labour had not made a threshold finding that there was a significant risk, as that phrase was used, at ten parts per million, and absent that finding it then couldn't proceed to promulgate a lower standard?

THE WITNESS: A. Yes. That the Secretary of Labour did not justify, in quotes, moving from ten parts per million to one part per million.

Q. I take it from what you are saying that, well, the thrust of the Supreme Court decision is that in making the finding of significant risk it would be very nice to have a risk assessment, there may nonetheless be some cases where you simply

Q. (cont'd.) can't do it, and the Secretary of Labour can still exercise his judgement or her judgement and make that finding.

DR. MUSTARD: Can I add another question to that?

As you stated very clearly, for substances which are suspected to be carcinogens, particularly those that are being introducednow, it would be very difficult to justify doing any human epidemiological study of exposing people to different dosage levels...at least I hope it would be difficult, I presume, to do that...the question that comes up is you then have to do animal experimentation, and having to do animal experimentation means that you are going to have to do all this, and when you do that you are going to have a best-estimate problem. That is, what you are going to do is try to make an estimate of what you think the risks are, and...but you'll have to admit that you could be higher or you could be lower.

Has that issue been debated at all within the regulatory agencies and the advocates of the different stances as to what steps should be taken there? Am I making myself clear?

THE WITNESS: No, I'm not clear.

DR. MUSTARD: Well, you have got to take an estimate from experiments in animals...

THE WITNESS: Yes.

DR. MUSTARD: ...and the dose-response relationship, say for rats...

THE WITNESS: Right.

DR. MUSTARD: ...could be different than for rabbits and for guinea pigs, and you will therefore have to draw some kind of curve that takes all that together.

Now, for human beings the risk relationship may be different still further - in other words, they may be higher or lower, a slighter curve or a steeper curve, and you have to

DR. MUSTARD: (cont'd.) make assumptions to do that, and therefore that is in a sense a best-estimate that you are going to make, and somebody could take the stance, well, why didn't you take it higher, why didn't you take it lower, in terms of the slope of the curve. Has that been debated at all?

THE WITNESS: Yes, it has, extensively. Yes, you are right.

DR. MUSTARD: What policies do you adopt to handle that one?

THE WITNESS: I don't think that the agency has arrived at a policy with respect to that.

MR. LASKIN: Q. Can I just...I'm sorry, Dr. Uffen.

DR. UFFEN: Could I just clear up one little thing that...

MR. LASKIN: Yes, sure.

DR. UFFEN: ...in the statement made just a minute ago. I think I've found a similar statement in this particularly good article of yours, number eleven.

"The court further stated that OSHA is not required to support its findings that significant risk exists with anything approaching scientific certainty"...and I believe you just said that...

THE WITNESS: Yes.

DR. UFFEN: "..so long as they are supported by a body of reputable scientific thought, the agency is free to use conservative assumptions in interpretating the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection".

Was that what the court said, or is that what you say?

THE WITNESS: That's what the court said, yes.

MR. LASKIN: Q. Could we just spend a few moments on this term 'significant risk'? Am I right, first of all, that that is not a phrase that comes out of the statute, per se, your statute? That's a phrase that comes out of a Supreme Court decision?

THE WITNESS: A. Yes, that's correct.

Q. Did the agency, in light of benzene, develop any criteria to separate or divide significant risk from insignificant risk, nonsignificant risk?

A. No. The agency has not. That is an issue that is being worked on in the agency, so whether or not six cancer deaths per year or ten cancer deaths per year are considered significant risk has really not been carefully addressed by the agency. While the court alluded to this...I'll have to get the specific language that the court used, one in a million, I think, they pointed out in one of their footnotes... there has not been a clear definition of significant risk.

One can speculate or suggest that the risk may depend upon the substance, that maybe what we define as a significant risk using risk assessment in the number for benzene may be different from the significant risk for vinyl chloride or some other substance.

So it's a difficult issue to grapple with and the agency has not, to my knowledge, come forward with any clear criteria as to what is a significant and what is an insignificant risk.

Q. Do you have any personal judgement on that question?

A. I would tend to the side of between one and ten to a thousand, in my view, would be significant.

In other words, if we say, okay, we calculate the probability of cancer from this substance is ten cases per

A. (cont'd.) thousand per year, in my own view I would move to regulate because that, in my own view, is a significant risk. Where maybe one in a million, I would say don't waste taxpayers' money, or don't waste industry's money trying to prevent one in a million. But when we are talking about ten per thousand population, per thousand workers, I would...

Q. Is there an exposure level built-in to that or is that an overall view? I mean ten out of a thousand per year, at what level of exposure?

A. At this, the low end of this spectrum...the level that we, quote, unquote, normally find in the workplace, not at the high animal dosage where we conduct our experiments.

I know that this is an area you get a lot of debate on...a lot of debate on.

DR. UFFEN: Would it be...wouldn't you have to have two definitions - significant, that we've been talking about, and acceptable - and then if significant exceed acceptable, it's got to be banned or action taken on it.

There are two definitions, to my mind, necessary.

THE WITNESS: Well, when you get into the question of acceptable - acceptable to whom? Acceptable to the government? Acceptable to industry? Acceptable to the worker who is exposed everyday? That's the problem that you have there.

DR. UFFEN: Then we have a third one. We have permissible. Permissible may be defined in law, acceptable may escape law, may escape any real definition because it's a value judgement.

THE WITNESS: Acceptable?

DR. UFFEN: Acceptable.

THE WITNESS: Yes.

DR. UFFEN: But we can define permissible, in law, by some method of measurement or monitoring?

THE WITNESS: Yes. Permissible when there is a threshold. In substances where we...let's take noncarcinogenic substances, one has a threshold where we say okay, below five parts per million...based on our evidence, there is no overt health effect. Then five parts per million and above is a permissible exposure limit - a PEL. And the courts have supported, basically, that deal.

But society may find when you throw all the societal factors in, it may find ten cases of cancer per thousand of population, per thousand workers, a year acceptable.

It may look at cost to reduce this to one, and say we do not want to spend X number of billions of dollars to save ten or to prevent ten cancers per thousand workers a year. That's the societal issue that I was trying to point out in my presentation earlier this morning - a very, very important issue. Really not a scientific issue.

MR. LASKIN: Q. Was the no-threshold for carcinogens, was that another issue, debated issue that the cancer policy attempted to put to rest?

THE WITNESS: A. Yes.

Q. So we have, in terms of the issues that the cancer policy attempted to deal with and put to rest for the time being as not being subject to being reargued in every specific substance rule-making proceeding, we have that issue - no threshold?

A. No threshold.

Q. Animal...

A. Extrapolation...

Q. ...versus human?

A. ...to human, yes.

Q. Okay. And then third, positive...

A. Nonpositive epidemiological data. We said

A. (cont'd.) that if the agency reviewed or accepted for review nonpositive epidemiological data, it had to meet certain criteria. The first criteria that it had to meet was that the period of exposure of the worker had to be twenty years. The observation period for that worker had to be thirty years, taking into consideration the latency factor.

We said the population size had to be such that it would show a fifty percent excess of the disease in the population. So you couldn't come in with a very small sample and say, heavens, I found five workers...I have studied five workers in this plant and none of these five workers show any evidence of asbestos-related disease. That's a very small population, and that's not acceptable. You had to have a much larger population such that you could show that, if there's a background, such that you could show a fifty percent excess of disease among the population.

Q. If it was there?

A. If it was there, yes. Yes. And what we were trying to do was to improve the quality of epidemiological studies, because the record of a number of OSHA standard...and the record is cloudy with bad epidemiological studies - very small populations, observation periods less than twenty years... and yet those studies would be put into the record, the agency had to analyze them. And we were saying in the cancer policy, do not submit to this agency epidemiological studies that do not meet specified criteria and additional criteria spelled out in the policy.

DR. MUSTARD: Can I ask you a question? Am I sure I'm hearing you clearly that you would accept as evidence epidemiolgical studies which were only of the size to be able to show a fifty percent mortality difference? You know, it may be how we are interpreting fifty percent, but most of the things

DR. MUSTARD: (cont'd.) we have been looking at we have been looking at shifts of...which may be slightly different than that, and more fine tuning...or is that fifty percent in relation to a very small increase in the number of deaths? I'm just not quite sure what you mean by the fifty percent.

THE WITNESS: Fifty percent increase in the incidence.

DR. MUSTARD: I see.

THE WITNESS: New cases of the disease, the incidence.

DR. MUSTARD: All right.

THE WITNESS: New cases of the disease.

MR. LASKIN: Q. How big would the population have to be if the study was negative, if it showed no adverse health effects from exposure to whatever the substance was? How big or small would the population have to be before OSHA would accept it as being some evidence upon which it could act or not act?

THE WITNESS: A. Oh, I think in the hundreds. In the hundreds. But not five workers in a small plant down the street.

Q. But I take it if the study was positive that that might be a different story? For example, we have had some quite small cohorts in the asbestos field, and I can think of the gas mask workers, for example, which is a very small cohort, but a very high incidence of asbestos-related disease. I take it that if the study is positive, that would be something the agency would accept?

A. We would review that. The question that...I mean the issue here was, if a representative came in with positive animal data on a substance and another representative presented us with nonpositive epidemiological data, which would we accept?

A. (cont'd.) We are saying that even...we wouldn't even review the nonpositive data unless it met these criteria.

Q. And even if it did, you may still accept the positive...

A. Positive animal data would still supercede negative, or nonpositive, epidemiological data.

DR. UFFEN: I'm sorry to have to do this, but I thought I understood and I am getting worried that I don't know what positive and nonpositive really mean. Could you just...?

THE WITNESS: Positive says that this study, the agent causes cancer. A nonpositive study would be the agent would not cause cancer.

DR. UFFEN: Ever, ever?

THE WITNESS: Based on a well-designed study with results showing that this agent does not cause cancer.

DR. UFFEN: Can I put my question another way? Have there been debates about things from one group or one individual who said I think this is a positive result, and somebody else says no, it's not positive?

THE WITNESS: Yes, yes.

DR. UFFEN: There's room for differences of opinion?

THE WITNESS: Yes, yes. In fact, in a number of cases we have had an epidemiologist employed by labour, and another epidemiologist employed by management, both looking at the same pieces of paper and coming to different conclusions - one was positive and the other one says no, it's nonpositive.

So that debate is ongoing.

MR. LASKIN: Q. Can we just turn to this term feasibility, which is a term which is used in the statute? Can you just...let me see if I understand it. As I understand

Q. (cont'd.) OSHA's original approach to the term feasibility, it was that feasibility from industry's point of view meant that, only that a standard would not be set so low that it would essentially mean the industry would have to close up. Other than that there was no real cost connotation, cost of compliance element, in the term feasibility under the statute.

Have I put that accurately or not?

A. I think the Supreme Court best defined feasibility as, can it be done...is the technology available, and can it be done in such a way that we will not wipe out an entire industry. Because we recognize that the Congress never intended for the Secretary of Labour to promulgate and implement standards that would wipe out entire industries.

Now, the technology question, there has been suggestions that the Occupational Health and Safety Act could drive technology, that the technology may not be readily available but it's on the horizon sort of thing, and that we could set the standard to move industry to adopt technology that was just on the horizon...that that could be put into place to control work exposure.

Q. How does the Supreme Court's interpretation of feasibility, and the OSHA's approach, how does it square with President Reagan's executive order? Are they reconcilable?

A. They are. Yes, they are reconcilable. Because the executive order is, in effect, saying that the cost-benefit analysis should be done. And one of the things that we do, or we did, in cost-benefit analysis is to look at feasibility. That was clear in the Act, and the Congress inpassing the Act struck that balance, as I indicated earlier.

So I don't see that they are irreconcilable.

Q. Without exploring this too deeply, would it not be possible to promulgate a standard which was, quote,

Q. (cont'd.) feasible, in the sense that industry can do it, but if you put a cost-benefit analysis on top of it, whatever cost-benefit analysis it was, you may find that the costs were way out of whack with the, quote, benefits, quote.

A. Yeah, I think that certainly is a possibility, but I think one of the things that has happened is, more often than not we have felt that cost-benefit analysis was designed to prevent or impede the regulatory process.

I think cost-benefit analysis can be used to look at the alternatives. For example, cost-benefit analysis can be used to determine whether or not we use engineering controls, or whether or not we simply use protective clothing or personal protective devices such as respirators and coveralls, and these kinds of protective devices.

So I think it can be used to look at alternatives.

Go ahead.

Q. Just on that very point, OSHA...OSHA did take a position on that issue between the work practices and engineering controls on the one hand, and personal protective devices on the other?

A. They did.

Q. They did? Which was?

A. And the agency's position has been that engineering controls are by far the most effective approach to reducing work exposure.

Q. What's the rationale behind that?

A. The rationale is engineering controls are long-term, quote, unquote, permanent kinds of controls, that it did not depend...egineering controls does not depend upon whether the respirator properly fits the worker's face, does not require the worker to participate extensively in protecting himself. It's a permanent kind of control, and it's far more

A. (cont'd.) reliable and effective in reducing work exposure.

Q. And has that issue been re-evaluated in light of the executive order?

A. That issue is up for re-evaluation now. The cotton dust generated...the cotton dust controversy raised anew the question of engineering controls versus personal protective equipment. But by and large most of the industrial hygienists feel engineering controls is the most effective...and in the long run...the most cost-effective way to reduce work exposure.

Q. I take it the agency is just really in the process right now of reconsidering that question?

A. The agency is now reconsidering that question, yes.

Q. What...can I ask you about another different issue, but I think it came up in one the early rule-making proceedings, and that is the use of labelling of toxic substances, use of warning signs in the workplace, information in the workplace. Did OSHA have a position on that?

A. Yes. The agency was strongly supportive of labelling. It was a part of the workers'-right-to-know package.

You may recall that we promulgated a rule that would make available to employees their medical records so that they would know what is in those medical records, etc. The other part of that workers'-right-to-know package was the right to know what the worker is exposed to and what hazards were involved, and it is important that workers have this kind of information because an occupational health program requires not only that management carry out their responsibilities, but workers must carry out certain responsibilities. And if workers are to effectively participate in reducing their exposure, in

A. (cont'd.) protecting their own health, then they had to know what they were working with and what they were exposed to.

If they knew, for example, that benzene or other substances are cancer-causing agents, they would be more apt to take necessary precautions in handling or otherwise managing those substances. So we thought it was a very important part of the workers', one, right to know, and an important part of his overall effort to protect himself in the workplace.

It was a powerful part of worker education and a lot of emphasis is being put on educating the worker, and certainly knowing what you are exposed to is a very, very important part of that program.

Q. Can I just come back to that cancer policy for a moment? Is it too soon to be able to tell, or do you have any judgement as to whether the cancer policy is going to solve, or is indeed solving some of the problems that led to its formation?

I mean, is there any assessment, for example, as to whether it is speeding up the promulgation of standards?

A. It is not, at this point, speeding up the promulgation of standards because the benzene decision seems to have raised some questions in the minds of some observers as to whether or not the cancer policy is consistent with the Supreme Court decision.

What is often overlooked is the fact that the cancer policy does not regulate a substance. The cancer policy simply says to the Secretary of Labour, if you are going to regulate a carcinogen, these are the criteria, these are the guidelines that you ought to follow, that you should follow.

So the cancer policy is now under review.

Q. The cancer policy itself?

A. The cancer policy itself is now under review in light of, one, the benzene decision, and two, the cotton dust

A. (cont'd.) decision on the whole question of cost benefit and feasibility.

DR. DUPRE: Could I inject here, counsel?

Dr. Walker, in my own mind I just feel a little need to slow down in order to try to appreciate, perhaps, more than I do at the moment exactly how, from the standpoint at least of the officials who designed it, a cancer policy that is supposed to work. Never mind the accidents that may or may not result from a court decision downstream, or something like that, but as I understand it, and I've done what homework I could - reading the original policy in the Federal Register and then looking at some of the subsequent Registers - as I understand it, quite in line with the considerations that you have already outlined, to reduce all of the repetition that was going on, under the policy there was first of all the business of producing candidate lists.

Now, from here, as I understand it, the next step would be priority lists. Is that correct?

THE WITNESS: That's correct.

DR. DUPRE: And the priority lists, of course, would be restricted in number, if I remember right, to about ten in each category?

THE WITNESS: Yes.

DR. DUPRE: Now, am I correct in understanding that once a substance is on the priority list it is not yet regulated?

THE WITNESS: No.

DR. DUPRE: There are further steps that have to be taken?

THE WITNESS: Once a substance is on the candidates list...I mean on the priority list...

DR. DUPRE: The priority list.

THE WITNESS: It is a candidate for regulatory action. It does not say that the Secretary ought to regulate them in the one, two order...

DR. DUPRE: Right.

THE WITNESS: ...but it says that these are the substances that the agency is focussing on from a regulatory standpoint. And why we did that was to try to reduce to some manageable size the substances that the agency should be looking at from a regulatory standpoint.

When we look at the whole list of potential carcinogens, ranging up to two thousand, we said let's, through a screening process, reduce that to at least ten substances, and that these would be the substances on which the agency would focus their attention.

Now, what did this do? This said to industry, and the people making those substances and workers exposed to them, that these are substances on which we have enough information to regulate, and that precautionary measures could be taken...should be saying to the industry it's not necessary for you to wait for us to regulate. We have solid, good evidence that these are cancer-causing agents, and therefore you ought to take regulatory action immediately - not wait for the agency to regulate.

Now, if we flip back just a step, on the candidates list these were substances on which, for which, the agency requested more information and needed more information.

There may, for example, have been one animal study and the agency said well, we would like to have more on these substances that are on the candidates list.

It also said to the industry that if you got information on these substances, bring it forward now so that we can either do one or two things - either we can delete it from the candidates list because the evidence is overwhelming

THE WITNESS: (cont'd.) that it is not a carcinogen, or we can strengthen the data base on which we regulate this substance. Or if it was a class two, category two carginogen, give us more information, if you've got positive information, and we'll move it up to category one. Or if you've got good, solid negative information, we'll take it off the list.

So it was our way of letting the public know what the agency was considering, what its priorities were and saying get your data base together if you are going to participate in the public hearing on this substance, here is adequate time and here is the information that we would like to have on this substance.

So it was a kind of screening process.

DR. DUPRE: Just to make sure I followed, a substance on the candidates list is a candidate from a priority list, right? But not necessarily for regulation. The priority list is a candidate for regulation. Is that correct?

THE WITNESS: I like to think of it as a football team where everybody can try out, but in the final analysis you have got only a few people who make that final eleven playing in the game. And this is exactly what we did here. We started with a large number...

DR. DUPRE: We start with these...it's like that camp that the New York Jets hold, if I remember right, sometime in the late spring...anybody...

THE WITNESS: Yes, yes.

DR. DUPRE: ...fans out of the stand can come and try out. That's then the priority list...

THE WITNESS: You may have conducted in your laboratory at home, in your basement, a study on a substance and present that information to us. It's a part of that candidates list. But under additional scrutiny, more careful

THE WITNESS: (cont'd.) scrutiny, that substance may fall off the candidates list.

That's why we said, we'll publish that list every year so that each year we will have an opportunity to review new information and that list, we would hope, each year would get shorter.

DR. DUPRE: Okay.

MR. LASKIN: Q. How big is it on an annual basis? On the average of a couple of hundred, couple of thousand?

THE WITNESS: About a hundred.

Now, obviously there were some things that we didn't put on that list. Tannic acid in tea we know causes cancer. We didn't put that on the list.

DR. DUPRE: Incidentally, am I correct in getting from my reading the impression that only one candidates list was ever published?

THE WITNESS: Only one candidates list was ever published.

DR. DUPRE: And no priority list has yet been published?

THE WITNESS: No priority list has been published.

DR. DUPRE: So when you are talking about, around a hundred substances, you are referring to the one candidate...

THE WITNESS: The one candidates list that we published.

DR. DUPRE: Of a hundred, right.

THE WITNESS: The other candidates list, the other lists have not been published pending the current review of the policy to determine its consistency with the Supreme Court decision.

DR. DUPRE: Now, could I just maybe now continue on with my questions, which are just meant to equip me with an understanding of how this was supposed to work?

MR. LASKIN: Sure.

DR. DUPRE: All right. Let's assume a priority list is now up - ten substances. Under the policy, as I would understand it, the Secretary can pick. So let's say the Secretary picks two and five. It's at this stage that those substances, number two and number five, are going to have standards applied to them under this policy, is that correct?

THE WITNESS: Yes. But I think I ought to add a footnote here, and that is that the Secretary had to look at a number of factors in determining whether or not he should pick two and five - number of workers exposed would obviously have to be taken into consideration.

DR. DUPRE: Right.

THE WITNESS: What other regulatory agencies were doing. For example, if the Environment Protection Agency or the Consumer Products Safety Commission was looking at asbestos and getting ready to take action on it, that would be a factor that the Secretary maybe would have to take into consideration in determining whether or not he ought to move to regulate asbestos in the workplace.

So there are a number of factors, and I have them on a slide if we can see those later on.

MR. LASKIN: We'll have to take a break and...

Q. Could I just make sure I understand that, just to follow that up? I take it that the only criteria for getting on the priority list in the first instance, is scientific evidence? That's the criteria? You don't need anything other than scientific evidence to determine whether a substance is or is not going to be on the priority list? It's the strength of the evidence?

THE WITNESS: A. Yes, that is one factor. But we also look at, again, whether or not...the number of workers

A. (cont'd.) exposed. For example, let's assume...

DR. DUPRE: Doesn't that determine who gets on the priority list?

MR. LASKIN: Q. Doesn't that determine the priority...

THE WITNESS: A. On the priority list.

Q. Yes.

A. On the priority list.

Q. Right. And then to determine the priorities on the list, to determine which is first and whichis second, isn't it at that stage that you then bring in number of workers exposed, and so on and so forth?

A. Yes, yes.

Q. But the Secretary, nonetheless, is not bound by the agency's assessment as to priority one, priority two, priority three? The Secretary can choose priority nine if he or she feels that it's warranted to promulgate a standard for priority nine?

A. Right. Yes.

Q. Is there two priority lists we are talking about? Is this category one and category two?

A. We initially started out with two priority lists, and we decided that we would only publish one priority list which would be category one. And we would solicit additional information on items that we would have put on priority list two in order to determine whether or not we ought to move some of them up into priority one, or completely delete them from the list.

Q. The candidates list?

A. The candidates list, yes.

MR. LASKIN: I'm sorry. I interrupted.

DR. DUPRE: Okay, so now I've got...once that substance has been...once the Secretary has made that decision on,

DR. DUPRE: (cont'd.) let's say, number two and number five, it's at that point that those substances enter the standard-setting process, and there you will have a substance-by-substance hearing in which the parties, at that stage, can mount whatever arguments they have, one way or the other?

THE WITNESS: That's correct.

DR. DUPRE: Now, in that sense was there any time-saving element that the cancer policy was meant to achieve, once you hit that standard setting? I see the time saving in terms of your tryout camps, so to speak, but once the regular season begins are you into a lengthy game once again?

THE WITNESS: One time-saving element would be the size of the record. That we would not develop a record and a lot of information that the agency could not use in the standard-setting process. There would not be pages and pages that the agency had to analyze on whether or not you could translate from, you can extrapolate from animals to man. There would not be the question of nonpositive epidemiological studies, unless they met the criteria spelled out. There would not be the issue of threshold. So that would substantially reduce the record that the agency had to analyze inorder to develop the standard.

DR. DUPRE: Because your animal extrapolation issue and your threshold issue had been laid to rest?

THE WITNESS: Right.

Now, let me confess that the full generic dimension of that policy was diminished when the evidence in the record was against model standards, because here is the way we intended that policy to work in actuality: Once we identified a substance as class one or category one carcinogen, immediately certain elements of a standard would go into effect - lowest feasible level, engineering controls, labelling, etc.

But that part was lost when we simply took the

THE WITNESS: (cont'd.) stance that these are model guidelines, and that each, the hearing on each standard would address the guidelines and then later these would be translated into specific regulations.

So from that standpoint we are on a substance-by-substance basis.

DR. DUPRE: And of course I take it that I can appreciate that the way this thing was designed, the authors of it did understand the amount of time that could be consumed because, of course, there is something else that I found very interesting here, that this policy provides for emergency, temporary standards, and of course it was through emergency, temporary standards...presumably...that the agency or the Secretary could be equipped to provide workers with protection in that interim period during which one of the lengthy regular season games is dragging on.

THE WITNESS: That's right.

DR. DUPRE: Now, of course, there was never any opportunity to use that part of the policy, was there?

THE WITNESS: No.

DR. DUPRE: Could I ask you this, and it may be an unfair question, but all questions are unfair in matters of public administration: Do you think that the emergency, temporary standard provisions could have worked under the Act?

THE WITNESS: Yes.

DR. DUPRE: First of all, with the benzene decision in place, or otherwise?

THE WITNESS: Yes, it could have worked under the Act. Yes, it could have worked under the Act.

DR. DUPRE: And this is because of the manner in which the Act itself...

THE WITNESS: You see, the emergency, temporary

THE WITNESS: (cont'd.) standard was designed to have the Secretary of Labour respond immediately to a perceived hazard, and the Act required that six months thereafter there would be a permanent standard in place.

So if we, in effect, presented evidence to the Secretary tonight that substance X causes cancer, X number of people have died, etc., etc., an emergency, temporary standard could be put into place.

DR. DUPRE: Oh, but...then under the Act that emergency, temporary standard could only be in place for six months?

THE WITNESS: For six months while a permanent standard was being put in place.

DR. DUPRE: Okay.

THE WITNESS: Under the emergency, temporary standard there was no public hearing.

DR. DUPRE: Right. Because that's the only way you can get the thing moving out.

THE WITNESS: That's right. Correct.

DR. DUPRE: But now can I ask you this, Dr. Walker? If the setting of a regular standard, in the setting where the agency had set an emergency, temporary standard, wound up taking longer than six months, was there a legislative means whereby the emergency standard could be renewed to cover the interval?

THE WITNESS: I don't remember the specific language of the Act with respect to that.

DR. DUPRE: I'm sure you appreciate the fact that my...

THE WITNESS: I understand, I understand.

DR. DUPRE: ...dealing with administrative mechanisms. If the emergency standard dies after six months,

DR. DUPRE: (cont'd.) you have, of course, a built-in incentive for whatever parties don't like it to simply talk it out in the six month period, so to speak, and then there would be a problem.

THE WITNESS: I might say here that one of the reasons why we hesitated to use the emergency standard more often was because of the six month time constraint, and the court was very, very sensitive to that and held us to it.

DR. DUPRE: So that if one were drafting legislation, then, one would want to watch that particular...

THE WITNESS: I think that is a very, very important comment that you've made. Yes.

DR. DUPRE: I've been speaking, trespassing too long on your time. Please..

MR. LASKIN: Perhaps we could take a short break. Dr. Walker has some slides and in the break we could put some slides up.

DR. DUPRE: Shall we break? Yes, until about twenty to four.

THE INQUIRY RECESSED

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THE INQUIRY RESUMED

DR. DUPRE: Dr. Walker, if you would indulge me before we have the slides...

THE WITNESS: Sure.

DR. DUPRE: ...I wonder if I could ask you one more question that arose right out of the dialogue we were having before the break.

THE WITNESS: Yes.

DR. DUPRE: My question is this, was the cancer policy intended exclusively for new substances, or was it also intended to provide a means whereby OSHA could signal that

DR. DUPRE: (cont'd.) certain substances, and it could be asbestos, which were already subject to a standard, were being examined as candidates for a revised standard? Was it intended?

THE WITNESS: Yes, yes.

DR. DUPRE: So that I...let me put it to you this way. As I understand, of course, the NIOSH and OSHA initiative to move down from the two fiber standard, these initiatives took place before this policy was published and put into place?

THE WITNESS: Yes.

DR. DUPRE: Had this policy been in place at the time that you would have wanted to have undertaken such an initiative, can I take it that asbestos could first of all be put on a candidates list...

THE WITNESS: Yes.

DR. DUPRE: ...and then be put on a priority list?

THE WITNESS: A priority list, that's correct.

DR. DUPRE: I see. And of course, it was through this method, among other things, that once again you would have hoped to reduce the amount of time that is consumed by the animal issue, the threshold issue...

THE WITNESS: Right. It also took into consideration the fact that seldom are standards complete. New studies periodically come along, either showing that that standard is too stringent or it's too weak, and thus the agency is required to review those standards and to make the appropriate adjustments. And this is why we were looking again at the asbestos standard, why we convened a NIOSH/OSHA work group to review new information on asbestos and recommend a new standard.

DR. DUPRE: Just one last question which simply pertains to the only candidates list that was ever issued: All I saw on that candidates list was the federal register issue of

DR. DUPRE: (cont'd.) August 12, 1980, which I then read pages fifty-three thousand, six seventy-two through fifty-three thousand, six seventy-four. But as I got to the end, I hadn't yet seen the list.

The list is prominently announced in the register. I can show you my own copy, if you want, but then I didn't see the actual substances.

THE WITNESS: I don't know what happened to your version of the list, because it was included.

DR. DUPRE: Oh, it just probably got blanked out by the xerox machine.

THE WITNESS: Yes.

DR. UFFEN: Would you remember the list?

THE WITNESS: Yes. Well, not exactly, but...

DR. UFFEN: Would you remember whether nicotine was on the list?

THE WITNESS: No, nicotine was not on the list. Sunshine that causes cancer was not on the list. Tannic acid in tea, which causes cancer, was not on the list.

MR. LASKIN: Q. What was the rationale for excluding some substances which you knew did cause cancer in different situations?

THE WITNESS: A. We were concerned about reducing occupationally-induced cancer, and nicotine, smoking cigarettes, is in any setting, you will find, and regulating nicotine would not have necessarily reduced occupationally-related cancer and our mission under the Act was occupationally-related cancer.

Q. Could I just ask you one, before we go to the slides, just one final question on this emergency, temporary standard which the Chairman was asking you about before the break?

A. Sure.

Q. Which I gather...and I gather the provision

Q. (cont'd.) for that is in the statute, and was in the statute, from the time it was first passed?

A. Yes.

Q. And requires an employee to be exposed to grave danger from exposure to substances or agents determined to be toxic, and that such emergency standard is necessary to protect the employees from such danger.

My question is, I couldn't find anything in the statute on this, is it open, for example, to a trade union to apply to the Secretary of Labour for an emergency, temporary standard?

A. Yes. The trade union movement in Washington, about three months ago, applied to the Secretary of Labour for an emergency, temporary standard on ethylene oxide.

Q. And having applied, what obligation, if any, is there on the Secretary to do anything about the application?

A. The Secretary can review the information for merit and make a determination as to whether or not the data available and submitted justifies the implementation of an emergency, temporary standard, or whether or not the condition can be corrected by a permanent standard procedure.

Q. And is that decision by the Secretary reviewable in any manner? Suppose the Secretary says, no, I don't accept the data and I don't accept the application, and I'm not going to do anything?

A. You can go to district court, federal court, and have that reviewed.

Q. It would be reviewed...it's capable of the same kind of judicial review that the promulgation of the permanent standard is?

A. That's correct.

DR. DUPRE: One other little matter of draftsmanship

DR. DUPRE: (cont'd.) that I would like to understand in case it has any lessons is the following: I note, of course, that in the wake of the benzene decision there had to be a number of deletions in certain paragraphs of the cancer policy. When all is said and done, these deletions largely involve always the same set of words, namely, "set as low as feasible" with respect to a standard.

Now, let me put it to you this way: To the extent that the candidates list and the priority list...if I may now revert to the athletic analogies of which I am so fond, if you will indulge me, Dr. Walker...to the extent that these were meant to streamline the training camp, was there any particular reason to have those words in at all where the candidates list or the priority list were concerned? Was the reason perhaps that by having those words in once again the intent was to contain the amount of time that a regular season game in the regulatory league, substance-by-substance...

THE WITNESS: The words you mean, 'lowest feasible level'?

DR. DUPRE: Yes.

THE WITNESS: The reason that they were put in there was to emphasize that we have not identified a threshold for carcinogens, and that we had to assume, therefore, that any amount...a tenth of a part per million, a tenth of a billion parts per million...would cause cancer.

Now, what the Supreme Court decision in effect did was to say that we would reduce it to the lowest feasible, lowest feasible level necessary to reduce significant risk, because the court has said you have to define a significant risk in order to promulgate a standard, and therefore if you are going to lower that standard, that standard has to be lowered to the lowest feasible level necessary to reduce that significant risk.

THE WITNESS: (cont'd.) And that's why the policy is undergoing review and will probably have to be amended to be consistent with the court decision, and say to the court, we heard your decision, we have read your decision, we are now attempting to respond to that decision.

MR. LASKIN: Perhaps we could turn to the slides.

THE WITNESS: Okay.

What I would like to do is briefly walk you through this document, which is a distillation of some two hundred and fifty thousand pages of public record, and here we see the major component of that policy and one could really call parts A and B, an encyclopedia on carcinogenesis, because here is a thorough discussion of the agency's rationale and need for the policy, a discussion of the use of human studies in identifying, in classifying potential occupational carcinogens, and here is where we, in effect, address all the argument for the use of human data in identifying and classifying potential occupational carcinogens.

Section C is a very thorough discussion of animal bioassays...the pros and cons of extrapolating from animal to man, the pros and cons of high dosage, the pros and cons of sensitive animals which was raised in a discussion that I had during the break.

Part D includes an analysis of the major regulatory issues, and the model guidelines that we had discussed earlier.

Part E is the regulatory text, and a very small part of the document.

In the regulatory process, we propose, submit to public hearing and then develop a final document based on the public hearing. Here's what we propose, as I indicated earlier, we proposed categories one, two, three and four, in the final policy they were deleted. We did not include in the proposal the scientific review panel. This is the panel that included the

THE WITNESS: (cont'd.) director of the National Cancer Institute, director of NIOSH, director of the National Institute of Environmental Health. This is the panel of experts on which the Secretary of Labour would call to address scientific issues about which there may be some controversy.

We did not include in the original cancer policy the candidates list which was discussed earlier, and finally in the proposal we listed model standards, and in the final document those standards were changed to guidelines.

In the original proposal that we submitted for public comment, we did not have a procedure for amending the policy, but during the public discussion there was much comment, many comments, I should say, about amending the policy, and we including those provisions that I cited earlier today.

I'm sorry, yes?

MR. LASKIN: Q. Just before you leave that, I'm not sure I understood model standards versus guidelines, and you may have covered it, but...

THE WITNESS: A. In model standards, once we determined that something was a category one carcinogen, we would automatically put into place a set of requirements - lowest feasible level, engineering controls, housekeeping, medical monitoring for the workers - all of that would automatically click into place on a model standard.

Q. Not a permissible exposure level?

A. I'm sorry?

Q. Not a numerical standard? Not a permissible exposure level, but other requirements?

A. Other requirements, yes. To achieve the permissible exposure level.

We changed those to model guidelines because there was a substantial amount of testimony that suggested that

A. (cont'd.) there may be provisions in the model standards that would not apply to all carcinogens, and therefore we would suggest guidelines and then when we move to the public hearing process, we would make the determination which of the guidelines would be translated into the permanent standards.

Q. The guidelines, I take it, would not carry with them the punitive provisions of the statute?

A. No.

Q. They would not be enforceable, they would be good work practices suggested to an employer, but if the employer chose not to follow them, there were no sanctions...at least until the standard...

A. That's right. Until the standard was in place, yes.

DR. DUPRE: But under the model standard approach, which was in the original proposal, there would have been enforcement teeth? That's the difference between a model standard and a model guideline?

THE WITNESS: Yes, yes.

And getting back to your ealier point about speeding up the process, once we identified a class one carcinogen, everybody knew that these were the standards that would apply...that you had to monitor the worker periodically, that you had to monitor the workplace, that there were certain housekeeping procedures that automatically clicked in. No debate, no long, drawn-out discussion about moral standards...a time-saving device.

DR. DUPRE: Yes. So that indeed you start to get protective devices like improved engineering or work practices in place...

THE WITNESS: Yes.

DR. DUPRE: While a regular season regulatory game is being played over the number that is going to be put in?

THE WITNESS: That's correct.

MR. LASKIN: Q. Just to finish that off, do I take it under the proposal that you had model standards, but those standards would not be subject to debate in the specific rule-making proceeding on the substance, that followed?

THE WITNESS: A. Right. Would not be, right.

Q. But under the guideline approach, it's open to the parties to attack the model guidelines to suggest this guideline shouldn't apply to the asbestos industry, or...

A. Yes. Under guidelines, for example, there could be extensive debate about whether or not sputum cytology is an effective early-detection method for lung cancer.

Or you could debate whether ot not the workplace should be vacuumed five times a day or three times a day.

Under the model standard, no debate is part of the standard.

Q. So there's those two differences - number one, the enforcement mechanism comes to bear on the standards, and number two, they are not open to debate in the rule-making procedure?

A. Correct.

Again, that's designed to speed up that process.

This was a basic timetable that we had set for implementation of the cancer policy, and you will see that the candidates list was drawn from several sources - the Environment Protection Agency had a list of carcinogens, suspected carcinogens, that it was concerned about in terms of air and water quality, the National Toxicological Program, the National Cancer Institute, the National Institute of Occupational Safety and Health, Food and Drug Administration had a list of suspected carcinogens, and

A. (cont'd.) a number of groups outside of the government had candidates that they submitted for that list.

This is how that candidates list was made up. It included information from all of these sources.

We subjected that list to an inhouse review by OSHA, inhouse staff screened it, then to the scientific review panel, and then to the Assistant Secretary for Occupational Safety and Health.

The candidates list, we then applied...sorry?

DR. UFFEN: Just to be clear, I think we might get confused between the scientific panel, review panel, and there was in the legislation a scientific advisory group. They are not the same thing?

THE WITNESS: No. The scientific review panel had a focus much narrower than an advisory group. The Occupational Health and Safety Act said that the Secretary of Labour 'may' convene an advisory group to advise him on a broad range of issues dealing with occupational safety and health.

For example, when we set the coke oven standard the Secretary of Labour appointed an advisory group to advise him on the data on coke oven emissions and the shape and the form that the standard should take.

This panel, the scientific review panel, has a much more narrow focus in that if there are issues that must be resolved, dealing with the identification and the classification of carcinogens, this scientific review panel - which includes the three directors of the three research institutes in federal establishments - would make up this panel, and the Secretary would submit that issue to the panel for resolution.

Let's assume, for example, that three studies, four studies, came in on a substance, and as the scientists looked at those studies there was basic disagreement - one said the

THE WITNESS: (cont'd.) epidemiological data suggested it is a carcinogen, another scientist said no, the evidence suggests no...we looked at statistical analysis, etc.

This scientific review panel would be the final, quote, unquote, auditor.

Now, there was much discussion in the public hearing about this scientific review.

DR. UFFEN: They were all government scientists?

THE WITNESS: They are, and that was the focus of the argument. There was much concern about narrowing that scope to governmental scientists. There was a recommendation that the National Academy of Sciences in the United States should be that body, but the agency decided that these were the well-recognized...National Cancer Institute, the National Institute of Occupational Safety and Health, and the National Institute of Environmental Health scientists...were the recognized agencies of the government and that these should be the people whom the Secretary should call on...that the Secretary of Labour should be able to call on the scientific establishment in the federal government for advice, rather than to have to go outside. And that was a legal question as to whether or not the Secretary could delegate that kind of responsibility to persons outside the federal establishment.

There is a very extensive record on that.

Yes?

DR. DUPRE: Just to make sure I understand the distinction, an advisory panel, on the other hand, could include extramural scientists?

THE WITNESS: Yes, correct.

This is simply the flow of the candidates list, where we would take that candidates list, apply the criteria for prioritization and at that point we were considering publishing

THE WITNESS: (cont'd.) categories one and categories two, the top ten in each list.

Sorry?

MR. LASKIN: Q. If that had gone through and there had been two categories, was it contemplated that there would be specific rule making on category two substances, or did you have to get up into category one before you were subject to a rule making?

THE WITNESS: A. The Secretary of Labour could have regulated substances in category two under his normal authority to control or to regulate toxic substances. He would have not had to regulate them under the provisions of the cancer policy, because the substances in category two did not have strong enough data base, a data base strong enough to put them in category one. But he could have regulated them as a toxic substance, and setting, in this case, a permissible exposure limit because as a toxic substance we would have had to identify a threshold level. But as a carcinogen, no.

Q. But does that mean it would still go through this lengthy adjudicative process?

A. Yes. Yes.

Q. What's the...

A. Some of the issues would not have been discussed again. The whole issue of animal data would have not been an issue here.

The whole idea behind category two was simply to say to the research community and industry at large, these are substances that we are kind of shaky on, we need more information, and if the federal establishment, for example, is giving out research money for cancer research, here are a list of substances that should be researched more. That was one of the driving forces behind category two.

A. (cont'd.) It would also say to industry that, here's a substance that we are looking at - we need more information. If you have information, pro or con, make it available to us so that we can make a determination to move it up into category one, or simply take it off the list the next time we publish it.

Now, I think you can well understand and well appreciate the fact that publishing the list caused much concern on the part of the industry - concern that we had blacklisted a substance before it was regulated, that if that substance was being supplied by an industry to a user, that that user may say, don't...I'm not buying any more of that stuff because it's on OSHA's list.

But that was a concern and it was discussed very extensively.

Here is basically the heart of the cancer policy - the definition of a potential carcinogen is any substance, mixture or combination of substances, or a metabolite of a substance, which does what - which "increases the incidence of tumors or decreases the latency period between exposure and onset of tumors in humans, or in one animal species, after all respiratory, abdominal exposure, or any exposure causing systematic tumors".

How do we then move from that to category one? The other criteria for category one: "Any substance found to be a potential occupational carcinogen in humans or one animal species, plus concordant evidence in the same species, a second study, or in another specie, or a short-term test, such as the Aim test or others, or injection or implementation site tumors, or one species without concordant

A. (cont'd.) "evidence, based on the Secretary's decision".

This was designed to give the Secretary of Labour some leeway in regulating these substances.

Category two - "A substance may be a potential occupational carcinogen because of suggested..." we are getting weaker..."suggested human or animal data, or positive results in one species only".

That is the heart of the cancer policy: definition of a carcinogen and the criteria used to categorize the substances.

Prioritization...we raised that earlier...the number of workers exposed, the estimated exposure levels, the levels of exposure shown to produce the tumor, whether or not it was two parts per million, five parts per million, etc...had to consider here the benefit to workers of reducing exposure level, and here's where the whole issue of cost benefit slides in without a lot of publicity.

The molecular similarity of the substance under consideration to a known carcinogen, whether or not there are safe substitutes available, the agency's responsibility for dealing with the hazard, and as I indicated earlier, action being taken by other agencies of the federal establishment.

DR. UFFEN: Was there any weighting system developed?

THE WITNESS: Yes, a very extensive weighting system was developed.

Positive versus nonpositive results: An issue we raised earlier, that positive animal results supercede nonpositive human data, that positive results in one species supercedes nonpositive data in another species, that positive results in one species will be given greater weight than nonpositive results, and provided the positive results are

THE WITNESS: (cont'd.) biologically and statistically significant, only one positive animal result would be considered in the brief scientific review of the candidate substances. The whole issue of positive versus nonpositive results.

Acceptance of nonpositive test results: And here the criteria, at least a twenty year worker exposure; thirty years of observations after the initial exposure, taking into consideration the whole question of latency; a group of exposed workers...that the group is large enough to detect that fifty percent increase above that in the unexposed control.

Acceptance of nonpositive test results...I won't bore you with this, but here are some of the criteria that we spelled out in the policy.

MR. LASKIN: With Dr. Walker's assistance, we might be able to reproduce those slides and distribute the photocopies to everyone.

DR. UFFEN: It makes it a lot easier than plowing through the great, thick...

MR. LASKIN: Q. I just have a few more questions, but there is one other matter that perhaps I should have covered earlier and I want to make sure I understand it, and this is just briefly to go through the rule-making process in the United States, and I just want to make sure that I understand, we understand, all of the steps involved in order on any specific substance under the statute.

I take it the first step is that the Secretary decides that he wants to promulgate a particular standard?

THE WITNESS: A. The Secretary may, on his own motion, decide that. He may be petitioned by industry, or he may be petitioned by labour to promulgate a standard. The Secretary will then review the data to determine whether or not it is sufficient to initiate rule making.

A. (cont'd.) He will then develop a proposal, and that proposal will be published in the Federal Register...

Q. Just stepping...in the process of that happening, is that where the NIOSH criteria document comes in, and the input of the advisory committees?

A. No.

Q. Maybe you could just run through that process?

A. The NIOSH criteria document may be one source of information that will start rule making. There may be information from other research agencies. There may be information from industry or other sources into the Secretary for him to make a determination as to whether or not we should proceed with rule making...there is enough data there to suggest that there is a hazard and that that hazard ought to be reduced.

Then the next step is to develop a proposal, and that proposal will in effect cover a PEL, a recommended PEL. The Secretary may say we propose to regulate at one part per million, based on our review of the evidence.

What will then happen also, simultaneously, will be an economic analysis..looking at the industry, looking at what it may cost to comply with a one part per million standard, etc. This will all, then, be published in the Federal Register, giving the public a substantial amount of time to review, and then we will move to a public hearing.

Then at the public hearing, all of the issues are examined. Everybody has an opportunity to come in and testify, witnesses are cross-examined, a record is established, and then the agency analyzes the record and then a final standard is promulgated.

Now, in the past there has always been court review, and the pattern has been industry will say the standard is too stringent, labour will say it's not stringent enough, and

A. (cont'd.) the court will usually review and make some determination.

This process has in the past often taken from one to three years, and one of the limiting factors has been the analysis of this very extensive record. In some cases the...well, in practically all cases...the agency, in the proposal, has asked very specific questions on which it wants comments. For example, should the level be at one, five, or at one, three or five.

It is also asked what should, for example, in the case of lung cancer, should sputum cytology be a part of the regular medical examination of the worker, and several questions of this kind.

We've also asked, relating to the cancer policy, about animal data and threshold, and we've also included questions with respect to epidemiological data.

More often than not in the past, this record had not given us the kind of information that we need to promulgate the standard. What we got...and I repeat the emphasis...was a number of epidemiological studies that were very poorly designed, did not meet the basic criteria for a good epidemiological study, but they were part of the record, they were analyzed, consumed a lot of time and really didn't give us the kind of information that we were hoping that we would get.

So this is basically the process.

Q. What did you do? Did OSHA do anything, being dissatisfied with the record it had?

A. Being dissatisfied with the record it had, the agency had to rely on the NIOSH scientists and the OSHA scientists to fill in the information that we were hoping to get from public participation.

Q. Where they...

A. Now, let me add, in some cases we have,

A. (cont'd.) unfortunately, had date omitted or left out of the record, only to have it submitted to the court...and I made that comment earlier. Where if we could have had it here, it could have been built in to the final standard and strengthened the agency's position...

DR. UFFEN: There is no provision for powers to subpoena documents and things like that, until you get to the court review?

THE WITNESS: The Secretary of Labour has seldom, if ever, used his subpoena authority. He could use it, it's available to him, but it was always felt that using subpoena authority would just exacerbate the adversarial relationship.

In the case of economic data, as I said in my earlier statement, the group that has the data on compliance are the people to be regulated, and we do not have access, ready access to those data, and we have hesitated to use the subpoena process, hoping that...well, we didn't want to further exacerbate the adversarial relationship.

MR. LASKIN: Q. But where does the advisory committee come into this structure?

THE WITNESS: A. The Secretary of Labour may, at this point...

Q. Which point?

A. At this point...convene an advisory committee to review these data.

Q. He may or may not?

A. He may or may not.

Q. And that is stipulated...

A. In many cases, if it's a very controversial issue, then he may convene the advisory council. But if it's clear cut, the evidence...there is no question about the evidence and no question about the soundness of the epidemiological and

A. (cont'd.) the animal studies, then we will move right from information to proposal to public hearing.

But if there is some controversy, some question about the quality of the data, a panel of experts, an advisory group, can be convened to advise the Secretary.

Q. Is there an environmental impact assessment that occurs somewhere in the process?

A. Yes. I should say economic and environmental impact assessment, yes. And both the economic analysis and the environment impact they have published with the proposal, and the public then has an opportunity...now not only to comment on the scientific and technical information, but on the economic and environmental data as well.

You may recall there was extensive review of the economic data on cotton dust.

Q. And the public hearing is before an administrative law judge?

A. Yes.

Q. What is his...his function is simply, I take it, to keep order? I mean, he doesn't write any decision, does he?

A. No, no.

Q. He conducts the proceedings?

A. Recognizes the witnesses and makes sure that the witnesses aren't badgered too much by attornies, and...

Q. We never do that.

A. ...so that there is an orderly process.

Q. And can anybody have standing?

A. He approves and seals this hearing record, and then we can move on to analyze it for translating the public standard.

Q. Can any member of the public appear, or do you have to show a particular interest?

A. Any member of the public can just call and get on the list, and you can hear.

Q. Can they cross-examine?

A. You can be cross-examined.

Q. Can I cross-examine other witnesses if I am an ordinary member of the public?

A. Yes, you can. Sure. You can stand up from the audience and say, I have a question for this witness.

Q. And I must be recognized?

A. You must be...the law judge will recognize you and you can ask your question. It's a very open and fair process.

DR. DUPRE: Once you have, Dr. Walker...I was going to say finally...once you have promulgated a final standard and a party then challenges that standard so that your court review process is triggered, is the promulgated standard in force?

THE WITNESS: No. If the court stays the promulgation of the standard, it is not in force.

DR. DUPRE: If the court stays it, but how much discretion does the court have in terms of ...

THE WITNESS: The court may, the court may say to OSHA do not enforce that standard until we have had an opportunity to review it.

MR. LASKIN: Q. What did it say in...did it do that in benzene?

THE WITNESS: A. Yes.

Q. It did stay it?

A. Yes.

DR. DUPRE: But the court always has the option not to stay it?

THE WITNESS: Yes. Well, the court may stay certain provisions of that standard. The court may say, do not

THE WITNESS: (cont'd.) enforce the medical monitoring part of that standard, or do not enforce the engineering control provision of that standard, but enforce the rest of it. It may stay it in part, or it may stay it in whole.

DR. DUPRE: Just in terms of the experience of the agency, have the courts tended to be very stringent and to stay most finally-promulgated standards, or have they tended to give the agency the benefit of the doubt, or is there no pattern?

THE WITNESS: There is a court...the District of Columbia Federal Court has been a court that has been understanding of the occupational issues. There are other courts, the Fifth Circuit that sits in the southern part of the state, has not been as understanding of occupational health issues as the court that sits in the District of Columbia. That's the best way I can put it with lawyers in the room.

MR. LEDERER: Have you ever applied for a job in the diplomatic corp?

MR. LASKIN: Q. The final standard must carry reasons with it, and then there must be a...you must justify it with written reasons?

THE WITNESS: Yes. Yes. Very extensive justification.

Q. As I understand it, there have been how many final standards promulgated in the existence of...since OSHA's existence, under this procedure?

A. Oh, I think it would approach fourteen or fifteen standards.

Q. And the major time component in this whole process is what? Is it the analysis of the record, or the public hearing stage, or are they both equally long?

A. It's really the analysis of the record, because that is the major part of all of this action - the proposal, the

A. (cont'd.) economic analysis, etc., and then with the input from the public you get this massive record that has to be analyzed to make sure that all points of view are considered.

If we didn't adopt industry's point of view, or labour's point of view, we've got to explain why.

Let's assume that industry came in and said, okay, instead of one part per million, it will be five parts per million. Instead of engineering controls, it ought to be protective clothing. We have got to present an argument as to why we did not accept that argument.

DR. UFFEN: To whom does that argument go, then? Suppose it didn't happen?

THE WITNESS: Suppose what?

DR. UFFEN: The analysis of the record and all the justification and everything, to whom does it go? To the secretary?

THE WITNESS: What, the analysis?

DR. UFFEN: Yes.

MR. LASKIN: This is the final...

THE WITNESS: It would be led to review.

DR. UFFEN: Oh, it's called for by the court?

THE WITNESS: It's reviewed by the court. If industry says that standard should have been one part per million, it should have been five instead of one, and we came in with substantial testimony to show that it should be, and the agency ignored it, then the court has the responsibility to either sustain us or to say industry is correct, it ought to be five.

MR. LASKIN: Q. Who actually does the analysis of the record? I mean, if it's asbestos do you have a little asbestos group of personnel within OSHA who take charge of

Q. (cont'd.) writing up the record?

THE WITNESS: A. Yes. We have an inhouse group, and we call on people in the federal status - National Cancer Institute, NIOSH, National Institute of Environmental Health Sciences - or we may even call in experts from outside the agency to participate in analyzing the record.

Q. Would there be labour or management groups in this little committee that's analyzing the record?

A. If they are experts in those fields, yes.

Q. Scientific experts?

A. Scientific experts, yes.

DR. DUPRE: Dr. Walker, one other question. To what extent is the challenge of standards in the courts occasioned by the wording of the OSHA statute as distinct from general, shall we say, judge-made principles of administrative law as distinct from constitutional considerations?

THE WITNESS: By the wording of the law?

DR. DUPRE: Mmm-hmm. If the OSHA Act was drafted... is there a provision in the OSHA Act that permits appeal to the court?

THE WITNESS: Yes. Yes, there is.

DR. DUPRE: In the absence of such a provision, is it likely that there would be somewhat less involvement with the courts, or is it just as likely that for...for other channels - either appeal to the constitution or to general court...

THE WITNESS: I think that many of the court reviews have been...and this is my own view and doesn't represent my government's view...I think many of the reviews took place because of a strategy of 'let's delay, let's go into court, let's draw this procedure out, we don't believe there is enough evidence to warrant regulating this substance'. And I think that, on the other hand, for labour to go in and say, well, the standard

THE WITNESS: (cont'd.) is not stringent enough - this group is saying it's too stringent, we say it's not stringent enough.

I think time after time, if one looks at the extensive court record as I have, that surfaces more than not.

MR. LASKIN: Q. How often does...

THE WITNESS: A. Because...I'm sorry.

Q. I was going to say, how often has a review been successful? I mean, apart from the benzene case which I take it the Supreme Court decision...

A. I think OSHA has had...

Q. ...has, did you misinterpret your statute...

A. OHSA has had a fairly good record in the District of Columbia court on its standards. I think the lead standard, while there were some problems, by and large I think that the District of Columbia court said the agency did what was proper.

Q. But it's...I mean, strictly speaking, not to be overly legalistic about it...it is a review rather than an appeal? I mean, leaving aside how laywers try to twist the fact that no evidence or not enough evidence is a reviewable matter, it is not, strictly speaking, an appeal on ther merit...

A. Often, I think, it's a review of this whole process leading up to this final standard - did we do everything we should have done in this process.

Q. And did you interpret...

A. And does this record support what we finally promulgated.

Q. And did you interpret your statute properly?

A. And did we interpret the statute correctly. Cotton dust, for example - did we interpret feasibility correctly when we said that the Congress had already struck that balance between cost and benefit.

MR. LASKIN: I think I should let some of my friends ask Dr. Walker some questions.

You've been patient with me, Dr. Walker.

DR. DUPRE: Miss Jolley, do you wish to go next, or...?

cross-EXAMINATION BY MISS JOLLEY

Q. I just have a number of questions, Dr...or a few questions, I should say.

The first one that concerned me was the evidence you gave this morning about the industry witholding critical evidence on the benzene. And...I mean, it concerns in labour in the sense that this is not a one-time occurrence, it has occurred before.

Is there anything that OSHA can do? I understand that the Secretary does have the power to...and you say you want to avoid adversarial roles...but given that this evidence has come out now, is there anything that can be done, other than to go through the whole process again, over benzene?

A. NO, there is not very much one can do in terms of a study or an evaluation underway in an industry. Industry can always say the data were not complete, we wanted to do the study over again, there are some defects in the study, etc., etc. So there's very little we can do to get those data from industry, or to prevent any manipulation of the data.

Now, I don't suggest for a minute that manipulation of data is widespread in the industry. I think, you know, we've got scientist friends in the industry who are honest or sincere, but there is some manipulation of data and what we call in the field sometimes 'defensive epidemiology'.

Q. Is the agency presently involved in promulgating a new benzene standard with this new evidence?

A. I think that a new standard is under review.

A. (cont'd.) There are several standards under review. They are looking at the data on, I believe, formaldehyde, ethylene oxide, benzene and several others.

Q. I was also interested in the whole issue of freezing science, because this is something we are concerned about as well is the promulgation of standards that stay with us for the rest of our lives, essentially. Is that, I understand that you were raising it in terms of the cancer policy, but is that true in your other standards as well, now, that groups can appeal to the Secretary of Labour to reconsider, say, for example the lead standard or whatever? Well, that's a fairly new standard, but say one of the older standards. Can groups appeal to the Secretary of Labour now?

A. Yes, yes.

Q. And will that be done, then, a reconsideration of the...?

A. It depends on the kind of information that is submitted...how much information is submitted, is there overwhelming evidence, for example, that the standard we set in lead is too low and that we are now seeing evidence of that in the workplace. The same is true with other standards.

That's why I said earlier, seldom is a standard complete because there is ongoing collection of data, and as new data becomes available I think the agency has a responsibility to review those data and to make adjustments in the standard.

Q. The other thing that you said which I found interesting, when we were talking about personal protective equipment versus engineering controls as a means of controlling, you said that in fact engineering controls were probably more cost-effective in the long run. I wonder if you could expand on that statement?

A. Yes. I think if one looks at simply the

A. (cont'd.) installation costs of engineering controls...and here let's take an example, let's take ventilation for example...that one-time cost for installing that ventilation system, in my view, is far less expensive and far more protective than having to buy again and again protective clothing that may wear out, respirators that probably do not fit properly and give a level of protection. I think it's, in the long run, far more effective to engineer the exposure out of the workplace than to rely on protective clothing and other protective equipment.

Q. The other thing that we in the labour movement have some...

A. You then, you know, each time you get a new person on the job you've got to train him to wear the respirator and train him to wear protective clothing, etc.

Q. Right.

A. But engineering controls, you don't really need that.

Q. The other area of standard setting that the trade union movement had some difficulty with is the whole setting of time-weighted averages, and there are a number of jurisdictions that are moving away from time-weighted averages or do not in fact use time-weighted averages, use maximum allowable levels.

Is there a controversy within the agency about this? I mean, is there a discussion going on about the possibility of moving away from time-weighted averages?

A. NO, not extensively. I read a presentation by a person from Canada, Mr. Appleby I believe his name is, who raised that issue, and to my knowledge that was the first time that I had heard the TWA issue raised.

And it's the logical approach to looking at conditions in the workplace, because during the eight-hour work period you may get this kind of situation, and while you may

A. (cont'd.) at some point during the eight hour work day exceed that PEL, the total work day is what you are concerned about...the eight hour work day, does that exposure exceed five parts per million over the eight hour period.

Q. But we had evidence submitted to this Royal Commission that perhaps intermittent high exposures were more dangerous than a long-term low exposure, because of overwhelming the defence mechanisms, and things like that.

I mean, do you have scientific evidence to indicate that a time-weighted average is a valid concept?

A. No.

Q. Because we have time-weighted averages over forty hours, which also concerns us.

A. No. There is not a substantial volume of scientific evidence.

Q. And then..

A. The peak consideration is an important one.

Q. The last area that I do want to raise with you is the whole...it was raised in one of your papers and you called it sensitivity, and we call it here hypersusceptibility, and I just want to ask you that OSHA's mandate was obviously not out to protect the hypersusceptible, but it's inherent, you said, in the legislation?

A. Yes, it was. Yes, it was. Because the legislation says that that workplace shall be such as to prevent or protect, I forget the exact language, of every...I'm paraphrasing...every person, which included the hypersusceptible, etc. It's fairly clear in the legislation.

Q. In a standard such as for lead, you have a medical removal level of fifty micrograms per litre of blood, for all workers. Does that mandate mean that you could not differentiate between male and, say, female workers of childbearing years?

A. That's correct.

Q. Right.

A. That's correct, yes.

Q. Our lead standard differentiates.

That's my final question. Thank you.

A. Yes, that's then, as you well know, a very sensitive issue in the States.

MISS JOLLEY: Yes. Very sensitive here as well. Thank you very much, Dr. Walker.

DR. DUPRE: Thank you, Miss Jolley.

Mr. Lederer?

MR. LEDERER: Thank you, Mr. Chairman.

CROSS-EXAMINATION BY MR. LEDERER

Q. Dr. Walker, I have very few questions for you, and I think I am right in generally characterizing them as being in a general, almost philosophical, vein in relation to the notion of regulation setting...at least at the outset, and then at the end I have just a few more specific items that I would like to raise with you.

As I understand the cancer policy, or the system that it puts in place, what you really have is a policy that begins with the defining of a hazard and then moves through so that at the end, at some stage, you have a regulation in place.

What I would like to do, if I can, is to step back to what I think may be a stage which comes even before that original defining of the hazard, and if I can just refer you quickly to two of your papers that have been provided to us, because in them I find a comment on which I think I can base this line of questioning.

If you look first of all at document number ten, and specifically at page three hundred and sixty-eight, which is the first page that we have been given, and I would like to look

Q. (cont'd.) at the lefthand column, the last full paragraph in that column, beginning with the words, "While there is general agreement"...

A. Yes.

Q. Do you have that?

MR. LEDERER: Mr. Chairman, perhaps it would be best if I simply read that into the record...

DR. DUPRE: Please.

MR. LEDERER: Then everybody would know exactly where I am.

DR. DUPRE: This is page three sixty-eight?

MR. LEDERER: Yes, sir.

"While there is general agreement that cancer is a relevant occupational health issue, and that efforts must be made to more effectively regulate workplace carcinogens, the percentage of all cancers attributable to occupations is vigorously debated.

For example, estimates developed by..." and I'm sorry if I'm mispronouncing the name...

THE WITNESS: Bridbord.

MR. LEDERER: Bridbord, thank you.

"...et al, conclude that occupationally-related cancer may account for twenty percent or more of total cancer mortality in forthcoming decades.

Cole estimated that a fraction of cancer that is occupationally-induced is less than fifteen percent and less than five percent for women.

Wynder and Gori present estimates of four percent for men and two percent for women.

If all these estimates are arranged in chronological order, an upward trend can be detected."

MR. LEDERER: Q. Now, if I can refer you to paper number eleven, there is a similar kind of paragraph on page one hundred and seventy-six...that's also the first page of that document...and again, Mr. Chairman if I may read it into the record. It is repetitious, but I think it might be helpful, nonetheless.

I'm just starting at the second last line of the middle of the three columns, Dr. Walker, with the words, "linked to this issue".

THE WITNESS: A. Yes.

Q. "Linked to this issue is the vigorous debate over the proportion of cancer of environmental origin, or more specifically for our purpose the proportion related to occupation. For example, government estimate places the fraction of cancer that is related to occupational factors at twenty to thirty-eight percent for the present decade and the near future. This estimate is based on data for workers exposed to certain carcinogens - asbestos, arsenic, benzene, chromates, nickel oxides and petroleum derivatives.

Previous estimates had been as low as one to five percent. Cole has suggested that less than fifteen percent of cancer in men is due to occupational exposure".

Now, first of all, I gather that that estimate of twenty to thirty-eight percent is not an estimate which has been published in any journal or any other documentation that would require peer review, at this point? Is that right?

A. No, it has not. It's a NIOSH, National Cancer Institute document. It has not been published in a professional journal.

Q. Can we agree then, just...sorry, I'm going to have to pick a position where I can see you.

Sorry. Can we agree, just for the sake of the discussion that we are having this afternoon, that as a practical matter the issue of the percentages of cancers that one finds in society, or in American society if that's your area of experience, that there would be some debate about the percentages that would be caused by occupational exposures?

A. That's correct.

Q. And can we agree that when governments, as the regulatory agencies, come to determine the resources that they want to put in to regulating these kinds of substances, that it is going to make sense for them to attempt to place the dangers of occupational exposures in a general context of other exposures that may occur in society?

For example, we may want to know what percentages of cancer deaths are caused by occupational exposures as opposed to exposures due to smoking, for example.

Am I making sense at this point?

A. No, you lost me.

Q. All right. What I'm after is this: When a government comes to allocate resources, it's going to, I presume...

A. Are you focussing on the priority question in terms of occupational versus nonoccupational exposure?

Q. No. I'm trying to take you back even before you start trying to identify hazards, and what I want to know is, when you come to allocate resources, can we agree that you are going to want to know the...let me try and rephrase that...what you are going to want to do is put the risks through occupational exposures into the context of the risk created by other exposures in society.

In other words, if it's a minimal risk you are not

Q. (cont'd.) going to want to use that much government resource to look after it. On the other hand, if it's a very large risk you are going to want to...

A. Yes, that's correct.

Q. Okay. I'm sorry to make that so convoluted, Mr. Chairman. Am I being understood by anybody other than myself?

DR. DUPRE: No, I think I understand the exact question you asked. Did you have an immediate followup to it?

MR. LEDERER: I'm going to find out in a minute.

DR. DUPRE: Okay. Because if you don't, I do, so that's...

MR. LEDERER: Well, let me try mine, and if it doesn't match with yours I will be happy to defer to you.

MR. LEDERER: Q. My point, frankly, Dr. Walker, is this: When this Commission comes to make its recommendations to the Province of Ontario, and when the province comes to consider what it should do with those recommendations, would you agree that there is going to be an essential piece of information that the government should have, and that is, it should have some notion of the context in which occupational hazards occur in this province?

THE WITNESS: A. Yes.

Q. And that that's going to have an effect on the resources that we allocate to deal with this problem?

A. It should be a factor.

Q. Is that...are we on...

DR. DUPRE: It's a great followup. I have a followup to it, if you were switching to another area.

MR. LEDERER: I defer to you, in a minute.

DR. DUPRE: Oh. Well the followup that I have is really this, Dr. Walker. As I would perceive it, the issue, for example in the federal American setting, of how much by way of

DR. DUPRE: (cont'd.) resources to devote to environmental health protection as distinct from occupational health, in a setting where OSHA is the labour and EPA...is an independent agency or in health and human resources?

THE WITNESS: It's an independent agency.

DR. DUPRE: Is an independent agency.

In a setting where EPA is an independent agency and OSHA is in labour, basically the whole consideration of from year to year what kind of resources to put in would be part and parcel of a normal budgetary process?

THE WITNESS: That's right. And I think it gets back to the point I made earlier. Really those decisions are really made in the political arena. It takes it out of the hands of the scientists. The Congress responds the way it feels that it should, looking at the total resource package - defence, occupational health, environmental health, other issues that the federal establishment must face.

DR. DUPRE: And of course I would be correct in saying this, that the appropriations committees of Congress can reach below the level of the department of labour to look at OSHA directly?

THE WITNESS: Yes.

DR. DUPRE: Just as they can look at EPA directly, because that's an independent agency.

THE WITNESS: Yes. It has oversight responsibility.

DR. DUPRE: Yes. Does that same feature apply at the executive end of the budget process, when the bureau of the budget is involved?

THE WITNESS: Yes, it does.

DR. DUPRE: Back to you, Mr. Lederer.

MR. LEDERER: Thank you, sir.

Dr. Walker, I think I've gotten the answer to my

MR. LEDERER: (cont'd.) next question from that series of questions from the chairman. Let me just see if I can confirm it.

MR. LEDERER: Q. I was going to ask you whether or not you could give us, from your experience, any advice on how to approach this preliminary problem, but I gather from what you are saying that it really is a problem that appears in a political context and it's a decision to be made by politicians and that you, in your role as a government scientist, would in effect take the money you get and do the best you can with it - to state it simply?

THE WITNESS: A. That's correct.

Q. Now, in the same area, I want to move along to move along to one more stage if I can, as I understand it...and I think this comes out of everything you said and again as a direct response to something the Chairman has just said...in the United States this is fundamentally a federal program - it's run by the federal government and it's funded by federal tax dollars, and by the total population of the United States which supports that tax dollar. Is that fair?

A. Yes.

Q. Okay. I'm sorry, I'm going to have to ask you for an answer because if I don't get one it won't come up on the transcriber's tape and then nobody will know whether we had a discussion or whether I was talking to myself.

Just leaving that for the moment, the program that has been put in place by the cancer policy as such, as I understand it, was designed to be a comprehensive policy in that over time you would address this entire problem, really, and look over time at differing carcinogenic elements which would find their way onto one of your two lists, and off or on, and eventually everything would be determined.

A. That's correct.

Q. Now, that, I presume, would take a lot of tax dollars over time. It's hardly a scientific term, 'a lot', but nonetheless. It means a big commitment in government resource and dollars, that's really my point. A commitment supported by two hundred and twenty million people, or however many people there are presently residing in the United States.

A. I would say it requires resources, and the question of whether or not it would require a lot of resources is debatable. We would hope, I think one of the things that we were hoping, was that once we published that candidates list and then on to the list of priorities, that industry would move to find a substitute for some of the cancer-causing agents, and therefore spare the regulatory agency of the need to regulate those substances.

Q. Let me try to put my question to you more directly, and if it hasn't been explained to you yet, let me say that I am here representing the provincial government and that's why I'm going to keep coming back to the problem that confronts them, and through them the Commission, I suppose.

Would you agree with me that given the fact that there are, I'm told, approximately nine million people living in this province, and there are two hundred and twenty million people living in the United States, that it would be difficult for this Commission to recommend...and if the Commission were to recommend it, for the province to enact...the kind of program that was enacted by the federal government of the United States for that entire country, simply based upon the fact that the tax dollars would not necessarily support that kind of comprehensive program?

A. No, I do not. I think this is a very sound policy, comprehensive, and an effective way to deal with cancer-causing agents.

DR. MUSTARD: Can I interject for a moment? In answering that question, I would appreciate it if you would break out your reply into three components. There is the cost of generating the scientific evidence, which is large, but does not have to be based in any specific location as long as it is available for everyone to use.

Secondly, there then is the process that you go through, which is definable, partly what you've gone through there, and then the third is the cost of the enforcement of whatever regulation is put forth.

I wonder if you could...do you have any feel for the rough impression of that cost distribution in your activity? I am particularly anxious to look at the latter two components, that is, the process that you use - regardless of where the data base comes from - and secondly, the enforcement aspect.

I think that's a more relevant question to the question you are posing.

MR. LEDERER: Yes, definitely.

THE WITNESS: I think if one looked at your last two comments - implementation and the cost of enforcement - I would suggest that it would depend to a large extent upon what enforcement strategies you may use.

A voluntary compliance approach may be an effective strategy...simply publicizing what information you know and attempting to get voluntary compliance may be an effective approach.

I understand there is joint labour/management committees here. This may be an avenue by which you can reduce some of the compliance costs. I think we are really talking about compliance costs and not enforcement costs, because merely because we put a stop sign on every corner doesn't mean we have to stand a policeman there, an enforcement officer.

MR. LEDERER: Q. If I might interject, Dr. Walker,

Q. (cont'd.) and if Dr. Mustard doesn't mind, do I understand you to be saying then, that given the peculiar situation that one would find in this particular jurisdiction, that there certainly would have to be...there could be cost saving and presumably, given the structures that are in place here, more efficient means of implementing this kind of policy here, and with that in mind at the very least you could foresee that there would be modifications to it?

THE WITNESS: A. Yes. You may look at several alternative compliance strategies that may achieve the same goal at a much lower cost than you would incur in the United States.

You know, you may not have the strong adversarial relationship that still permeates labour/management in the States.

Q. I'm trying to figure out how to read Miss Jolley's groan when I asked that question.

I'm not sure, Dr. Mustard, whether Dr. Walker has fully replied to your question or whether...

DR. MUSTARD: He has given me enough of an answer.

DR. DUPRE: On the first...the first cost, of course, is, Dr. Mustard, is the cost of scientific evidence which, of course, is bound to, in many ways, the...I think... probably is more econimically done in, of course, the jurisdiction that is as large as the American federal government.

THE WITNESS: I think that would depend upon how much scientific evidence you are looking for. The Occupational Health and Safety Act says that the Secretary of Labour shall develop a standard based on the best available evidence.

If the best available evidence happens to be two animal studies, then the Secretary of Labour can promulgate the standard on the basis of two animal studies - recognizing again, as I said earlier, we will seldom have all the information necessary on which to set a standard.

DR. DUPRE: But now, Dr. Walker...

THE WITNESS: I think when we look at carcinogens there is a vast amount of research that has already been done, and still an extensive amount of research already underway with new information coming out almost quarterly on carcinogens.

DR. DUPRE: One thing I'm very much bearing in mind, Dr. Walker, of course, is your experience at state and local levels of government. From the state and local perspectives, have you found as a public health official that scientific information is quite readily available from federal sources?

THE WITNESS : Yes, yes. In fact, it's interesting, yesterday I just received from the National Toxicological Program its lists of carcinogens for 1981, and so that information is readily available to state and local levels in the United States.

DR. DUPRE: Now, is it readily available because of any particular statutory missions that the federal agencies involved have been given? Have they been exclusively directed to make as much information as possible available?

THE WITNESS: In the general context of keeping the public informed, educating the public, education...especially in the area of occupational health, educating the workers. These general provisions are in the statutes.

DR. DUPRE: And the statutesyou are referring to...?

THE WITNESS: Are the various, the Clean Air Act, the Occupational Safety and Health Act, Toxic Substance Control Act, etc.

DR. DUPRE: Thank you.

Excuse me, Mr. Lederer.

MR. LEDERER: Thank you, Mr. Chairman.

MR. LEDERER: Q. Quite apart from the allocation of resources that the province may have to make in this situation, as I understand it what theoretically happens is that if the cancer

Q. (cont'd.) policy that you have produced for us today and have discussed with us today, were in place in the United States and active, I gather it has been stayed at the moment, and if taking your answer to my...your initial answer to my last series of questions...it might be that this province would put in its own policy of a similar type, and presumably other jurisdictions would do the same, and I'm just wondering whether it doesn't strike you that there might be in that kind of situation an awful lot of duplication that might not be entirely necessary?

THE WITNESS: A. Yes. I think it would certainly be more productive to have such policies cover a wider geographical area.

Q. The reason I asked that is, there was a time in my career when I knew a little bit more than I can remember now about what was being done in the area of exposures to low level radiation, but what I do remember is that in that area there was an awful lot of international work going on, and in fact as I recall it under the United Nations there was an agency that was looking to publishing guidelines of a type for standards in that area, and I'm just wondering if you can tell us whether or not there is any kind of international organization, be it the United Nations or anything else, that may be investigating carcinogens in the more general context than merely exposures to radiation, and if not, whether you can foresee that that kind of program might be useful, and just exactly how it may be structured?

A. We have IARC, the International Agency for Research in Cancer, that is identifying, evaluating animal data and epidemiological data, and making some determination with respect to carcinogenicity of these substances.

But not from a regulatory standpoint.

Q. Can you foresee that such an international approach might be useful, might bear some fruit and might avoid the kind of duplication that may occur if we had a series of...

A. No, I think what we will see is an agreement upon the criteria for what is and what is not a carcinogen, that if we in the United States accept two well-designed animal studies as evidence of carcinogenicity, that the European countries and others would also accept it. I see a move in that direction.

Q. Now, with respect to the particular approach that is represented in the cancer policy, I take it that since no priority list has ever been published, that as a practical matter the policy hasn't been fully tested in the sense that you can't say to us that it has practically been employed from the beginning to the end, to this stage?

A. No, it has not. I has not been.

Q. I take it from something you said earlier that you are confident that it would work?

A. I am confident that if this policy were to be put in place that it would work. It would do what it was designed to do, and that was to speed up the regulatory process to address, or at least to prevent, at least minimize, rearguing and relitigation of the same issues time and time again.

Q. Am I right in saying that the policy was, generally speaking, constructed with the American system of government in mind?

A. We were trying to address an issue that we faced in the United States. There is no question about that.

Q. My only point is, that just as there might be modifications to it in relation to resources that are available, might there also be modifications in it to meet the system of government that one finds in this province?

A. That would be a logical conclusion, yes.

Q. And given the fact that it has never been... I assume that you will agree with me that many times when the government, any government, initiates a new policy, that policy, after it has been in place for a period of time, requires some kind of fine tuning...it doesn't work quite the way it was anticipated?

A. Mid-course review.

Q. Yes. And I presume that you would be prepared to concede that this policy, while, as you said, it would work, it would probably be subject to that kind of review and changes might well be made to it once...so that there is another area which may lead to some form of modification in the policy at some time in the future?

A. Yes, that's possible.

Q. I would like to refer you to the policy if I could, just to one of the paragraphs...paragraph one nine nine zero point one one two, which you'll find on page five thousand, two hundred and eighty-four.

There's so many pages to this I'm tempted to ask whether it's a good book or not, but...

A. The first part of it is basically a textbook on carcinogenesis.

I'm sorry, the page number again?

Q. I'm sorry. Five thousand, two hundred and eighty-four.

A. Okay.

Q. It's the paragraph entitled Classification of Potential Carcinogens.

Now, just before we look at the paragraph, one of the things that I took from your talk this morning was that there are really two elements that may play a role in a process like this. One is the technical, scientific input, and the other is

Q. (cont'd.) the social or political input. Is that, first of all, a fair dichotomy?

A. Sure.

Q. All right. The second thing that I understood you to say, and it may not be fair, which is why I raised it now, was that as a practical matter you identify the hazard, you priorize the hazard and then when you move into the substance-specific regulation process, you move into the sociopolitical area.

Now, am I right in understanding your view to be that those two inputs occur at discreet times in the process? In other words, you have...what that would mean is, you have pure science up until you have priorized the hazards, and then pure social and politics from that point forward?

A. No, I don't think it's that clean cut. I think you get a mixture of both the social, political along the process...certainly at the front end of this one looks very carefully at the scientific data. Certainly in determining risk, for example, one has to look at the animal data, carry on extrapolations, come up with some number indicating the probability of the development of cancer at a given level of the substance.

I think the political element comes, the sociopolitical element, comes in in determing whether or not society determines or feels, rather, that this is an acceptable risk or not acceptable risk.

Q. Well, I thought you would tell me that it was mixed, and the reason that I'm raising the question, it relates to the paragraph that I preferred you to, is that by my count there are three, I think, it may be four, references within that paragraph - which is sort of the initial stage, as I understand it, of the identification process - three references to the Secretary determines.

Q. (cont'd.) Now, the secretary is a political appointee, and though he may have and obviously does have, from what you have told us, technical input to his decisions, I presume that any decision he makes has a certain political component to it. The decisions he makes are meant to support the administration in place, are they not?

A. It may. It may in some cases.

Q. Okay. What this takes me to is what I...and this is a personal comment and as such probably doesn't have much place here...but what I perceive as being a real complication in all of this, and that is the interaction between politics and science.

Now, first of all, do you perceive that as a problem?

A. I think it could be. It could be a problem, yes.

Q. Would you be prepared to say that in those references to the Secretary determines, that I've referred you to within that paragraph, that there may be a political component to whatever it is he determines in any specific case?

A. Policital considerations may enter into that determination.

Q. And that those political considerations may, again within a given case that we don't have before us, may override certain scientific considerations?

A. It may, yes.

Q. Now, one of the things that, as I say, interests me is this interaction between science and politics and I would just like to discuss with you how that may or may not take place, and let me give you three examples that...I was going to say that I have come up with, but I can tell you that that would be taking too much credit...three that we've discussed, and let me put them to you and then, I think you've mentioned a couple, let me ask

Q. (cont'd.) you whether or not this is the kind of thing you mean...there can be Royal Commissions like this one in which the government designates, as they have here, three commissioners with certain legislative power to inquire into and assist them by giving them advice. They may also operate under a more ad hoc committee form in which the responsible government authority may simply go out and look for three or four people qualified in the field and say would you mind coming in and meeting with us once a month and we'll have a conversation, and the other one is in between the two, I suppose, a kind of formalized adversary...sorry, advisory committee...it's my lawyer's experience coming through again...formalized advisory committees who may have some recognition within the legislative process, but won't have all the formalized powers that this Commission does, and that I take it, is the kind of committee that was in place under the cancer policy.

Now, what I'm curious to know is whether or not you find that a satisfactory interaction between politics and science, or whether there is some other process or some other tool that I've missed or that we've missed that might assist in that part of the process?

A. No, I think the advisory committee approach can be an effective approach. I don't know the political dimension that you raise. I'm not sure I get the drift of how this advisory committee may be a part of that political process, because we are talking about an advisory committee of quote, unquote, experts in a given field who would advise the Secretary on scientific data.

I think the political dimention comes in when we translate that scientific data into an exposure level or number which then requires a compliance strategy on the part of industry, which then requires an expenditure of dollars which may impact on

A. (cont'd.) industry or impact on the economy of the country as a whole, or on a geographical area. That is where the political dimension of this comes in.

MR. LEDERER: Mr. Chairman, could I just have a moment?

DR. DUPRE: Yes.

MR. LEDERER: Thank you.

MR. LEDERER: Q. I think I understand what you are saying and I think it's something I can agree with. I'm just trying to rephrase it to see if I've got it right.

What you are talking about is a sort of natural continuum which starts with science, moves to a certain point... there may be an overlap, but moves to a certain point, begins to look at other considerations and comes out at the end with an answer which is a regulation. And in coming to that final answer, science will be a factor, a very important factor, but not necessarily the only factor.

Is that a fair assessment of what you have just said?

THE WITNESS: A. Yes.

Q. Okay. And I guess what I'm after, and I don't want to belabour this unnecessarily...Mr. Chairman, if this is wasting your time, I'm...

DR. DUPRE: Proceed.

MR. LEDERER: Q. What interests me is where in the process the other factors...where and how in the process those other factors and the scientific factors get played off against each other, and what the tools are that allow for that to happen?

THE WITNESS: A. I think in one area the whole cost-benefit question played them off. Where we arrive at a cost of complicance and we are faced with the question as to

A. (cont'd.) whether or not the prevention of X number of cases of lung cancer and colon cancer, or whatever, is worth the cost of developing a new ventilation system in a plant, installing a new ventilation system, or other kinds of engineering measures in that plant. That is one area in which it is played off.

I cited to you...well, I cited to you the example earlier, at least I cited to the group, the example earlier of how a risk analysis may show that the probability of...the probability is about ninety-nine percent that the population exposed to very low levels of...on the lower end of the scale, I was talking about...low levels of a cancer-causing agent, the probability is ninety-nine percent that ten cases per thousand workers would develop each year. Now, that becomes a...while I may see from a public health standpoint that is a significant number, the political process may say that, my God, we cannot spend a billion dollars to save only ten lives or to prevent only ten cases of disease.

I think that constant shifting and balancing is a part of this regulatory process.

Q. Can I assume that you are confident that the cancer policy would have met that...would have dealt with those two elements appropriately, had it continued in place?

A. I believe it would have, yes.

Q. Now, I'm going to move out of what I think I said at the beginning were more general-area questions, and there are just a couple of...well, I shouldn't say a couple, but a few more specific points and then hopefully I won't take too much longer.

What I would like to do is to start again and refer you quickly to a couple of paragraphs in some of the papers you have given us, and in this case it would be paper

Q. (cont'd.) eleven and paper eight. With paper eleven if we could look at page one seventy-six, that would be the page we were at before, and you will recall I read you a paragraph starting at the bottom of the middle of the page. I would like to read you the immediately preceding paragraph, all right?

THE WITNESS: A. Yes.

Q. "Although records are maintained on causes of death in the nation, and several state and regional cancer registries have been functioning for many years, there has been no national reporting system to define the incidence of cancer in the country as a whole. At the national level, the Department of Health and Human Services surveillance system, with limited geographic coverage, has provided data for incidence estimates only since 1969 for white populations, and 1974 for blacks."

Then, in paper number eight, a similar comment on page one twenty-seven...and you'll find this also in the middle of the three columns, and this is the second last paragraph in that column, beginning with the words 'governmental health'.

Do you see that, Dr. Walker?

A. Page one twenty...I'm sorry?

Q. Twenty-seven.

A. One twenty-seven? Okay. "Governmental health agencies."

Q. Yes.

"The Governmental Health Agency has the resources of an ongoing intelligence system because it functions as the community bookkeeper of health, and therefore knows how many people are born, how many die. It knows what people die of, which diseases are important killers, which are increasing

Q. (cont'd.) "and which are decreasing, can identify death rates by occupational groups, age, sex and economic status so that vulnerable sections of the population can be identified."

Now, is there in the United States presently, or in any jurisdiction within the United States, (a) a recording system which will record either the mortality or morbidity in relation to cancers? Is there something that specific?

A. Yes, there is. A number of jurisdictions in the United States have cancer registries that will give us the incidence of cancer. There is a very comprehensive reporting system of deaths in the United States. Every state has a state registrar, an office of vital statistics, that keeps records of deaths and births, and on the death certificates the underlying cause of death is stated. And so those systems are in place.

Q. Now, given the facts that what we are dealing with here is cancers found from occupational exposures to asbestos, and remembering the initial question I raised with you about, you know, placing occupational cancers in a context of general societal exposure, to make use of this kind of information in relation to the problem that we are dealing with, doyou not have to have...and if you do, is there in existence... any data or documentation accompanying these records which will link the cancers to exposures? In other words, link the cancer in a particular death to the occupational setting of that person when they were alive?

In fairness to you, that's a two-part question... firstly, don't you need it, and secondly, does it exist, and I guess thirdly, if it doesn't exist is there some way in which it practically could be made to exist?

A. Yeah, I think retrospective epidemiological studies would allow us to do that, and having said that I must

A. (cont'd.) also indicate some of the weaknesses in trying to conduct retrospective epidemiological studies - to take a death certificate, if you will, and try to work back to exposure, length of employment, etc., etc., - is not an easy task.

But some general inferences can be drawn from that kind of an analysis.

I think your earlier question was don't you really need a definition of a problem.

Q. Yes.

A. And I would say, yes, one has to have some definition of a problem.

Q. Now, I guess you have indicated that these records may be helpful in the sense that you could do this kind of epidemiological study from them. I gather from what you said earlier and what you are saying now that that kind of study is somewhat limited, because you don't have direct exposures you only have more indirect comments, like the length of employment and that sort of thing.

May I ask you whether or not in fact any jurisdiction in the United States presently keeps that kind of record...that is, what I would call a linkage record?

A. California's system. We are establishing one in Michigan. I think New York State has such a system. A number of our major industrial states have such data.

Q. Okay.

A. And NIOSH, at the national level, has been and is continuing to collect such data.

Q. What I presume that means is that the employer, for example, would have to keep some records as to who they employed and when they employed them?

A. Yes.

Q. My question, I suppose, is, since you have said

Q. (cont'd.) such records should be kept, firstly who would keep them? Is it the employer who keeps them, and what does he do with them?

A. Larger employers with inhouse occupational health programs usually will have these kinds of data available.

Q. Is it your view that they should be forwarded from there to some kind of central recording agency, like the government, for example?

A. It should be made available to the government, yes.

Q. We have talked...I have used the term linkage.. I guess that has a special meaning in American foreign policy right now, doesn't it. I'm almost afraid I've used it.

Can you tell me...I've used that in a very general context..can you tell me ideally, with an eye to practicality, what kind of information you want to see in a recording system like that?

A. One would want to see, obviously, exposure data, because if you are trying to show an association between a given disease, then exposure data becomes very, very important.

So exposure data is important, and that's one of the reasons why in all of our standards, in all the OSHA standards, the requirement for monitoring the workplace and medical monitoring of the worker is very, very important, because that data base will help us, one, to determine whether or not the standard that we have in place is effective.

Q. Just one other, I think very brief question, in that area. Who would that kind of information be open to?

A. Certainly, I think, the governmental agencies, the regulatory agencies which have the responsibility for worker protection should have that information.

Q. Okay. Can...

A. The workers themselves ought to have that information available to them.

Q. Can we move now back to the policy, and to... well, I don't know that I'm going to refer you specifically to it, but it's paragraph one nine nine zero point one three two, and that's the...that and the paragraph just preceding it is the one which talks about the compilation of the priority lists and the two lists which...

A. Page Fifty-two zero seven?

Q. Fifty-two eighty-five.

A. Candidates list and priorities?

Q. Fifty-two eighty-five, I have it at. Sorry.

A. Okay.

Q. I think this is going to sound a little simple, but it is of some significance to me...I don't know if it is to anybody else, and if it sounds a little simple I would appreciate it if you would just bear with me.

It ties into my question about the comprehensive nature of your plan. What this policy assumes, to be blunt about it, is that there is something that needs regulation, doesn't it?

A. Yes.

Q. I mean, the fact of the matter is that if there were something which, in a practical context...sorry, if there were nothing in a practical context at loose in Toronto, that caused serious cancers, if this policy were in place nonetheless we would be working things through, because it's a continuous program, wouldn't we?

A. If the agency had not defined the problem that it was trying to resolve with this policy, we would have never promulgated such...

Q. I see. And does that refer in part back to the things you need to make the list - the one in a million...when

Q. (cont'd.) you showed the slides, and I know it's a direct quote out of the policy itself of what it is that you have to have before you can get on the list...is that the kind of thing you are referring to?

A. The definition problem?

Q. Yes.

A. No.

Q. I'm sorry. I'm missing something.

A. I'm referring...you probably don't have the introduction to the cancer policy...the four hundred thousand American deaths from cancer that occurred in 1977, more than a thousand persons per day. That's the definition of the cancer problem that we were facing.

Q. To just review one point very quickly with you, that I think you made with Mr. Laskin, just to be sure that I understand it, you went through with him the way in which standards might be reviewed, and you gave us three examples - the Secretary can do it on his own, a petition can go to the Secretary, and I've forgotten the third one now...

A. A criteria document from NIOSH may generate that standard.

Q. And it's that way, it's through that process and that process only, I gather, that your list keeps up to date with scientific developments...your regulations and lists keep up to date with scientific developments?

A. You mean those sources of information?

Q. Yes.

A. There may be many other sources of information.

Q. No, but if you have a standard at one part per million, and new data is developed which demonstrates that actually you should have a standard of five parts per million or point five parts per million, moving either way, it's through that process...

A. Through that process that we raise or lower the standards?

Q. Yes.

A. Yes. That's correct.

Q. Thank you.

Oh, there's one other, I think sensitive area, that I would like to review with you. You've talked about public input to this kind of process, and you've talked about where in the process public input comes. Have you ever confronted a problem or been part of a problem where it has been your perception as a scientist that public outcry over a given substance has far outweighed the scientific justification for that outcry?

A. Yes.

Q. And can you indicate to me how you would recommend that kind of situation be dealt with, in your experience?

A. A careful interpretation of the scientific data to the public. A comprehensive public information system that translates scientific data into terms understandable by the public.

I would not hesitate to say that I think it was an impression at one time that practically everything caused cancer, because picking up the daily newspapers there was a substance of the week, as we often said. I think there is misinformation in the public arena and I think we as scientists have a responsibility to correct some of the misconceptions that are out there about, specifically, cancer-causing agents.

Q. And beyond that, would I be assuming that we would be getting into the political sphere and you would want to leave that to a politician to deal with? What you talked about is the scientists' responsibility to deal with that problem. Can you say anything about the manner in which the political element might want to deal with it, given your public service career?

A. Well, I think we have a responsibility to educate the politicians. Part of our problem has been that many of the health issues have moved from the clinical / medical arena into the political/legal arena, and the political/legal arena, the rules of debate are somewhat different. In that arena, exaggeration is often accepted as a practice. In the scientific/ medical community, exaggeration is at least frowned upon. I think we are facing that problem in some areas.

Q. Is that...

A. And I think it often hampers our effort to clearly define a problem and carry out the necessary regulatory strategies to deal with it.

Q. Is this an area where...going back to the discussion we had earlier...is this an area where the interaction between the political/social element and the scientific element can become crucial?

A. Very crucial, yes.

Q. You have indicated...well, again at the risk of being a bit simplistic, but just to lead into this properly... different government agencies are going to deal with elements or chemicals that have carcinogenic properties, is that correct? And they'll deal with them in different context, depending upon what their mandate responsibility is?

A. You mean food versus water and air, versus occupational...

Q. That kind of thing.

A. Yes. Yes.

Q. And they may, given the particular kind of exposures which their area mandate may subject people to, may have different kinds of standards...different standards...different kinds, I'm not sure if that's fair...different standards?

An ambient air standard is going to be different

Q. (cont'd.) from a drinking water standard, for example. Is that fair?

(no audible response.)

Q. Is there a program within your experience in the United States, is there a program which ensures a co-ordinated approach to the delineation of standards?

A. Yes, there was. The inter-agency regulatory group that included the Consumer Products Safety Commission who were concerned about consumer products, the Environmental Protection Agency concerned about the natural environment, the Occupational Safety and Health Administration, the Food and Drug Administration. All of these agencies were members of the Inter-agency Regulatory Group. In fact, the umbrella cancer policy under which the Occupational Health and Safety Administration policy was developed was developed by this Inter-agency Group. So we all agreed that yes, animal data can be applied to human populations, and we all agreed that there are... we haven't been able to detect a threshold level, and we all agreed on what is a good animal study and what is a good epidemiological study.

So we agreed on the basic elements of the regulatory process.

Q. You also, and I profess my ignorance to the American constitutional system...do you also have different levels of government having separate responsibilities in this area?

A. Standards by and large in the occupational area...

Q. Well, I'm thinking...I'm sorry, I would like you to apply your mind more generally as we just did in relation to inter-agency relationships. What I'm really after here is, is there a similar plan for co-ordination among various levels

Q. (cont'd.) of government, as well as among the various agencies of the federal government?

A. Yes, there is.

Q. Can I assume that you would agree that that is helpful?

A. Very helpful.

Q. Perhaps even necessary, again to avoid duplication and inconsistencies?

A. Very, very important.

Q. I presume as well, since there is going to be new data generated in this area as time goes on, that you would agree that there has to be some form of continuing research?

A. Yes.

Q. And I would be curious to know whether or not you think government agency has any particular role to play in that research, either in the performing of the research in its own laboratories, in the setting of research priorities for other institutions, in funding, in effect in any way, does the government have a role to play in that area, and if so, in your view what is that role?

A. All of the above. I think it has the responsibility not only to carry out research, but set national research priorities, as well as provide support for those in the private sector, in academic institutions, that may wish to carry out that research.

In fact, that was one of the driving forces behind our efforts to set priorities in terms of the substances that we were looking at.

Q. Just a general question. Would you want to see the money, the funding that was used for such research, directed to specific specialized institutions, or would you want to see it more generally distributed so that differing

Q. (cont'd.) views could be obtained, or do you see that as a particular question at all?

A. No, I would think it productive to have different views on these issues.

Q. Can you tell us in your view, given the current state of the art, what you think the present research priorities ought to be?

A. I think we certainly need to continue our efforts in the area of carcinogenesis. I think the whole area of reproductive effects has to be given a high priority. I think there is evidence to suggest that there are problems in the workplace with agents which may affect the whole reproductive system, and I think that should be given a high priority in our research efforts.

Q. You have indicated a couple of times this afternoon that you think that worker education programs are helpful. What I would like to know is firstly, what is a satisfactory worker education program, and I want to know quite frankly in your experience whether you think they work, and whether or not it is your view that the government has any particular role to play in relation to that aspect of dealing with the problem?

A. Yeah, I think it has worked very well in a number of industries in the United States. I don't think it can be accomplished by a film every week, every other week, shown to a group of workers. I think it has to be an ongoing activity. It must include information to the worker, and I'm speaking specifically of information to the worker on what he or she is exposed to, what the monitoring information shows in terms of his exposure, how he or she can protect himself, not only in the workplace, but outside of that occupational setting.

I think there are any number of combinations of

A. (cont'd.) strategies that an employer can use to effectively train his employees, and I think there are a number of places where that has been very, very effective.

Q. Is there a government role to play in those programs?

A. Government, in my view, has a very important role to play. I think we have been very effective in training managers and supervisors in workplaces so that they are in a position to, or can effectively, train employees under their supervisions. We have funded training programs put on by unions in our special grants area. We have given money to unions to develop pamphlets and carry out a comprehensive training program.

So I think government has an important role to play in that area.

Q. Since you mentioned distribution of pamphlets to unions, does the nonunion plant provide you with any particularly larger problem in this area - the area of worker education?

A. Oh, I think it does, I think it does. It's sometimes much more difficult to reach the nonunion group than it is to reach the union group, and expose them to educational efforts.

Q. I just have one other area that I want to ask you about. I presume that this whole business of exposure in the workplace is a fairly widespread one, you find it spread out throughout the United States, it's not restricted to any particular geographic area. Is that fair?

A. I think you will find there are concentrations. For example, in the petrochemical industry in the southwest and northeast, the whole exposure is far more critical than in some of the farming regions of our country.

Q. It's spread out over large areas, without saying the whole country?

A. Large areas.

Q. Now, in those areas the workers who are exposed are presumably going to have at their disposal any number of professionals that they may see - family doctors, or whatever, am I right about that, too?

A. They may.

Q. All right. My question is, given the complexity of this problem, do you perceive that there is a problem, are you satisfied that the professional organizations such as the family practitioner are suitably or appropriately informed as to these problems so that they can deal with them when they are confronted with them?

A. No. I think...if we have identified a major gap in the training of physicians in our country, that gap has been the lack of attention to occupational-related diseases and environment-related diseases.

MR. LEDERER: Thank you very much, Dr. Walker. If you will permit me, I have one other point I want to make with the Chairman, something of a personal comment.

I want to say to you, sir, that your reference to football today has thrown me off entirely. I thought baseball was your game and I'm going to have to completely re-evaluate my approach to this thing.

DR. DUPRE: All spectator sports are my game.

MR. LEDERER: I'm sorry, Mr. Gladstone may have one other...could I just have a moment? I apologize.

DR. DUPRE: Please.

MR. LEDERER: Q. Dr. Walker, I assume that when you were talking about the evaluations of risk, you used the figure of ten in a thousand might be considered to be a significant...you would consider to be...I presume that was an arbitrary figure that you used just for the purposes of discussion?

THE WITNESS: A. Just an arbitrary figure. Yes.

MR. LEDERER: Thank you very much, Mr. Chairman. I apologize.

DR. DUPRE: Dr. Mustard?

DR. MUSTARD: I want to go back to your significant risk, your reference to acceptable risk, and the issue which you brought up about chemicals and new chemicals.

If you are, in effect, going to introduce a policy, are introducing a policy that compounds will be screened for the biological effects, and if you find a chemical that is to be introduced is positive in terms of causing cancer, by the assay systems you have set up, you now face a problem. It seems to me you have three options that you can do, how you can handle this substance. One, you could ban its use if there is a substitute for it. Two, you could allow its use, but regulate it so that there is some...there is no risk to the worker, adopt the premise that it can be used, but that it must be used in a manner in which there is no risk to workers. Thirdly, you can go into the fact you allow its use, and from your animal exposure data you would project some risk assessment curve and then you would go through however you define significant or acceptable risk and allow its use under those terms.

Now, is there any clear policy developed in the United States as to how to handle this question? Have they developed a clear set of guidelines as to how they are going to allow new chemicals to be put into operation?

THE WITNESS: Yes. Under the Toxic Substance Control Act, the Environmental Protection Agency, there is a policy with respect to the use of these substances. In fact, the industry must show that these substances are not carcinogenic.

DR. MUSTARD: What if we suppose the substance is a carcinogen and I still wish to introduce it. What, then, do you do to me?

THE WITNESS: Then the option is to ban or set a permissible exposure limit. You may be aware of the efforts now in the United States to ban urea formaldehyde foam, an insulating agent.

OSHA has seldom used the banning authority. We have always tried to set a permissible exposure limit. We have taken into consideration the economic aspects, and felt that we could, with the co-operation of industry, reduce the level of exposure such that we can minimize the hazard.

DR. MUSTARD: Okay, now let me expand this problem a bit further and ask whether you have any assessments, or the United States have any assessment within its agencies about an additional problem. I realize that when you did your articles that you referred to the incidence of cancer, the Doll and Peto assessment of contributions of cancer was not available - which I guess was down at the U.S. Office of Technology or something - which comes out with a maximum likelihood estimate that four percent of cancers are related to the workplace, and it went up to about eight percent. That still is a significant figure in Ontario. Percentages are not really the issue here.

The most important point I think that they made in their article, from a scientific point of view, with an impact on public policy, is they conclude that really there is no satisfactory or treatment or cure for the majority of internal cancers, and therefore if one is really going to address the cancer issue, you have to address the source point, the cause of cancer.

That poses then a very difficult dilemma, I would think, in the policy-making machinery, because if you are concerned about cancer and you are prepared to invest large sums of money in treatment facilities, from the public purse, and on

DR. MUSTARD: (cont'd.) the other side of the coin...and the limitations, only to spell it in spades to you, in terms of the real impact on the curve side...if we go back on the other side of the coin, then maybe you have to address the prevention side.

Now, if you have got screening systems that allow you to determine whether a substance is a carcinogen or not, in acceptable biological definitions of it, how can you come to what an acceptable risk is in under those terms, because you are faced with the dilemma that exposure carries a risk - at least on the things that you put on board. I mean, you start to do a cost-benefit equation, you've got to put on the other side of the coin all those other costs over there.

Have you gone through that kind of problem and tried to work those figures through and come up with some kind of guideline that people can live with? Or is it...

THE WITNESS: I think in some isolated cases we have, but as I said earlier I think there are two kinds of acceptability - and that is the scientific/medical acceptability, and the whole political/societal acceptability.

I indicated that from a scientific standpoint I would consider ten cases per one thousand workers as unacceptable. But translate that, put that in the political/economic arena, it may be viewed as acceptable.

DR. MUSTARD: All right. Let me then put a third point onto this and ask you if you have another question on this one.

Some of us view the revolution that is taking place in industrial technology as a very important point in this equation. The ability to design isolation systems, computer control systems, remote control systems, has expanded enormously in the last fifteen years.

Has the agency ever looked at the cost of that

DR. MUSTARD: (cont'd.) technology in terms of its development and application in new processes where you introduce some new chemicals, and, say, applying that into your analysis so that in effect you can say that if you do introduce.. and let me give you an example in our own jurisdiction. We have a large number of nuclear power plants here, and they are currently, I believe, having some discussions, at least with an agency that makes the space arm on Columbia...and of course which is like an arm, and the calculations are that they can probably reduce radiation exposure of people changing the tubes in the plants by more than seventy percent by just bringing that device in, and obviously there is some kind of cost equation estimate that has to go into that.

Have you taken a look at the use of chemicals in industry with the philosophy that you can introduce new plants using control systems and remote control systems which in effect would achieve virtually zero exposure to known carcinogens?

THE WITNESS: Yes.

DR. MUSTARD: That would have impact...the impact that would have on your regulatory policy?

THE WITNESS: Yes.

DR. MUSTARD: Is that documented somewhere?

THE WITNESS: I believe it is, and I couldn't give you the exact citation now. But some of that work has been done.

DR. MUSTARD: I would appreciate it very much if we could get access to that evidence, because it seems to me in terms of the box you are in about new carcinogens that you have to face, I believe, the question of the control technology...

THE WITNESS: Yes. In fact I think there are several plants where the flow and processing of chemicals are controlled from a central computer unit, and there is very

THE WITNESS: (cont'd.) little exposure in some of these plants, of workers to these toxic agents.

DR. MUSTARD: Thank you.

DR. DUPRE: Dr. Walker, I don't want to detain you unduly but I would like to beg your indulgence for just really two hopefully very brief lines of questioning.

The first line begins with the dialogue you were having with Mr. Lederer concerning the whole problem of setting priorities in a carcinogen policy. I just wonder if I could pick your brains a little bit with respect to the dilemmas that perhaps asbestos as a substance seems to pose in this regard.

Asbestos quite clearly is a substance that proves to be very hazardous as a workplace substance. As you know, however, the more information came into the public domain on the extent to which asbestos is indeed an occupational hazard, the more, of course, we found ground for some very real apprehensions about asbestos as an environmental hazard.

Now, to the extent that asbestos...and this would mean, of course, very low levels of exposure in relation to the workplace...is indeed an environmental hazard in schools, public buildings and so on, to that extent, of course, if this is so, is it certainly desirable to have asbestos control programs which, of course, if they are mounted with the sense of priority that the environmental hazards may command, can outstrip the capacity of any kind of an occupational health regime to, of course, protect the health of the control workers who are involved.

Now, I guess that in a prescriptive kind of way what I'm asking myself out loud and what I want to pick your brains on are questions like the following: To what extent can one devise a carcinogen-identification policy that might be sensitive to the relevant hazards of a substance in the workplace,

DR. DUPRE: (cont'd.) as distinct from in the environment? To what extent are there perhaps certain kinds of concepts that may complicate the issues of having up this kind of relative hazard?

For example, to what extent is perhaps the concept of no-threshold very valid in the regulation, perhaps, of occupational health...a concept which carried over into the environmental situation where, of course, you may be looking at exposure levels that are so low that they are almost the same as the background exposure levels, a complicating factor?

Are there ways of, in other words, trying to sort out the extent to which substances may have quite different implications in the workplace as opposed to the environment, and is the extent to which the environment in the workplace from time to time entangled, a product of the way concepts have been applied for one or the other?

THE WITNESS: Yes, I think one can look at the whole question of relative risk in terms of the workplace where the exposures may be, for eight hours, much higher than in the nonoccupational setting where the exposures may be intermittent.

I think one can evaluate that and arrive at some reasonable priority as to whether or not resources ought to be... more resources ought to be put into reducing occupational exposure as opposed to a nonoccupational exposure.

One has to also look at the population at risk. In the workplace one could say by and large healthy males, in some cases, in the occupational setting...that may not be true any longer because there are females in the work force too...as opposed to in the nonoccupational setting where you have a full spectrum ranging from infants to the elderly, and a main factor in all of this...not that I...I think you can feed this into some kind of equation, into some kind of model, and come out

THE WITNESS: (cont'd.) with an answer at the end, but I think one is left with balancing and looking at all of these elements and making some determination as to where our resources can achieve the most return...where can we get the maximum protection for a given expenditure of public dollars?

I think that's where we merge the scientific and political/economic decisions. It's not an easy one.

DR. DUPRE: As I look at North American jurisdictions that I have any familiarity with, it seems to me that, well, I fail to find a decision making point, even on an advisory basis, where these kinds of considerations can really come to the fore. When I bear in mind that most of the jurisdictions with which I am familiar will tend to have, say an occupational agency with, of course, an occupational hazard identification list, an environmental agency with that kind of a focus...for that matter, a general public health agency, I have been looking for something that I haven't found. Have you...am I missing something?

THE WITNESS: In some communities we have heard the leadership of the policy makers in that community say if we've got dollars to invest in an environmental program, I want to make sure we remove the asbestos from the schools - that is the future generation, and if we destroy their basic biological structure now, we've in effect destroyed the future generation.

I think we've seen a lot of emphasis put on reproductive hazards, because here we are talking about effects onto the mother, and sometimes the father, as well as the offspring. But I don't think there is any clear-cut, neat formula that you can plug in some numbers and get an answer. It's an ongoing balance and evaluation kind of process, and I think it requires a multiple-discipline approach. It cannot all be decided by politicians, and not all by the scientists, but an interaction of those disciplines to come up with some resolution of that issue.

DR. DUPRE: At the interpolitical level in Washington, were you aware of any particular kinds of interagency liaison, say among NIOSH, OSHA, EPA, that would be looking at this question of the relative hazardousness of substances in the workplace, as distinct from the environment, as distinct from general health considerations?

THE WITNESS: I have no say no.

DR. DUPRE: Quite probably because it would be a waste of time...

THE WITNESS: Strike that, strike that. Yes, there was an effort on the part of OSHA and EPA to take a look at this. In fact, on a number of occasions we have said, if we control it in the workplace, what effect would it have on the environment? If we control it in the workplace, would it have an impact on the water supply, would it have an impact on air resources? Yes, this was done. This was an ongoing relationship.

In fact, we convened...I personally convened a meeting with the EPA on the cancer policy, examining these kinds of issues. Yes.

DR. DUPRE: And did you take these initiatives simply as the matter arose, or would it have been more useful to you if you want to take some initiative if there had been some facilitating provisions, either in legislation or something else?

THE WITNESS: If there had been some facilitating mandate from Congress or from the executive branch, I think it would have been far more productive.

DR. DUPRE: What kind of mandate would you have been looking for, Dr. Walker? A directive that EPA and OSHA should do what, liaise regularly, have a formal interagency committee?

THE WITNESS: Yes, that EPA, OSHA and other

THE WITNESS: (cont'd.) regulatory...should have a formal process to review common concerns and issues and come up with some resolution of the problems that should be solved.

DR. DUPRE: Some kind of interagency committee on the hazard identification?

THE WITNESS: Yes.

DR. DUPRE: The other question, long question I have is again, I hope, very brief, but I am...

THE WITNESS: Let me say that we were moving in that direction with the Interagency Regulatory Group...the IRLG which I referred to earlier. That was not a mandated group. It was a group of administrators who felt that it was important that we pool our efforts and resources and look at the kinds of issues that you have described.

DR. DUPRE: The IARG...

THE WITNESS: IRLG...Interagency Regulatory Liaison Group.

DR. DUPRE: In capital letters. I mean, it is set up by formal agreement among the agencies...

THE WITNESS: By formal agreement among agencies, the agency heads, yes.

DR. DUPRE: Is there...

THE WITNESS: In fact the formaldehyde document was a product of the Interagency work group, and there is a general cancer policy developed by that group.

DR. DUPRE: Now, if one wanted to trace the creation of that group, would find the record in the Federal Register, some kind of announcement that this...

THE WITNESS: There is a record that the Assistant Secretary of Labour, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Products Safety Commission, met, agreed to develop an agreement as to how things

THE WITNESS: (cont'd.) would be done. There is such a document.

DR. DUPRE: We could find the text of that document in the Federal Register? It's a public document?

THE WITNESS: In the Federal Register, yes. It's a public document.

DR. DUPRE: Roughly what year did you imagine that might be?

THE WITNESS: The...President Carter came into office when...the beginning of the Carter administration.

DR. DUPRE: So it would be in early 1977.

THE WITNESS: Early seventy...I remember issues by administration.

DR. DUPRE: The other matter pressing I have, Dr. Walker, simply has to do with the inspectional side of OSHA.

Now, as I...am I correct in understanding that the basic OSHA approach to inspection is to send in both a safety specialist and an industrial hygienist to do the inspection?

THE WITNESS: Yes.

DR. DUPRE: So you have really for inspectional purposes one force for safety, the other force for health?

THE WITNESS: Yes. There has long been an effort to try to reduce that to one. OSHA for a long time operated with safety inspectors. Industrial hygienists are difficult to recruit. There are not that many industrial hygienists.

But I think OSHA has now tried to increase the industrial hygiene manpower, but yes, there are two - a safety person and an industrial hygienist who go out...

DR. DUPRE: As someone who was, of course, on the health standards side of the industry, and just given your general knowledge, can I ask you this - which do you think is

DR. DUPRE: (cont'd.) the better direction in which to go, to try to encourage the development of competent, parallel safety and health inspection forces, or to try as much as possible to combine...

THE WITNESS: I think the desirable approach would be to train industrial hygienists to identify safety hazards. So that one inspector can go into that plant and evaluate both safety problems, as well as the power to set up the monitoring equipment, to measure toxic substances and be able to interpret those data to management, etc.

But I think...

DR. DUPRE: You don't think it can be done the other way around, though, to train a safety inspector to do the hygienist's job?

THE WITNESS: It depends to a large extent upon the safety, the background of that safety inspector. The industrial hygienists, as you probably know, come from either the scientific or the engineering discipline, and I guess I have a personal preference for training the industrial hygienist to recognize safety hazards. That's just my own personal bias, I guess.

DR. DUPRE: As an alternative possibility, does it make sense, perhaps, to think of a situation where the safety inspectors, or an inspectorate that was largely safety oriented, could be developed to the point where they would know when and how to call in a health inspector?

THE WITNESS: Yes, yes. Yes, I think that could be done. Sure.

DR. DUPRE: Is it likely, from your experience, that perhaps, given the relative qualifications, the relative number of persons already in place in inspectional forces, that this is the most practicable and feasible way of doing things?

THE WITNESS: I think it's practical and economical.

DR. DUPRE: More so, perhaps, than trying to have two fully-fledged and parallel inspectional forces?

THE WITNESS: Yes.

DR. DUPRE: And the idea would be to have the safety people really up front calling in the industrial hygientists, rather than the other way around? Is that what...

THE WITNESS: I would prefer to see...if I had a recommendation to make, it would be to train the industrial hygienists to identify and make recommendations for correcting the safety hazards, rather than having it the other way around... or rather than have two separate persons going in to a plant and making evaluations.

DR. DUPRE: Counsel, any further questions?

MR. LASKIN: I don't believe so, Mr. Chairman, other than to thank our witness.

DR. DUPRE: Well, Dr. Walker, I greeted you as a most distinguished public servant who has indeed served Dayton, Cleveland, the District of Columbia, New Jersey, Michigan, the U.S. Federal Government. I think that I speak for all here when I say that you could add Ontario to the notch of jurisdictions that you have served in spades after your most useful contribution today, sir. Thank you very, very much.

THE WITNESS: Mr. Chairman, thank you for the invitation to be here.

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THE INQUIRY ADJOURNED

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